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No. _____

IN THE

# SUPREME COURT OF THE UNITED STATES

October Term, 1984

ERNEST STICH and MIRIAM STICH,
*Petitioners*

*v.*

UNITED STATES OF AMERICA,
*Respondent*

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

## PETITION FOR WRIT OF CERTIORARI AND APPENDIX

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## QUESTIONS PRESENTED

In 1976, the United States instituted the largest government-sponsored immunization program in the country's history. In the face of a presumably imminent epidemic of swine flu, Congress, at the President's urging, hurriedly appropriated $135,000,000 to inoculate each man, woman and child in the United States against this influenza. In its efforts to immunize every American citizen, the government launched an unprecedented publicity campaign. It portrayed swine flu immunization as the patriotic duty of all Americans and dramatized the importance and safety of the immunization program by having the President of the United States inoculated on national television. To further entice participation in the program, the government assumed liability to its citizens for any injuries caused by the inoculation and agreed to promptly and equitably handle injured citizens' claims. Thus, the government made a pact with its citizens — if they agreed to participate in the inoculation program and further agreed, if injury resulted, to relinquish their right to trial by jury and their right to proceed against the drug manufacturers or other third parties, the government would agree to accept the liability and to compensate them.

In passing the Swine Flu Act, Congress entrusted the Attorney General with handling the claims of inoculation victims. Charged with the duty of administering the claims, the Justice Department adopted an extreme adversarial posture, "directing the government's efforts primarily toward litigation, rather than streamlined compensation of victims of the mass immunization program." Note, "Statutory Modification and Assumption of Private Liability: The Nuclear Energy And Flu Immunization Programs", 40 U.Pitt.L.Rev. 487, 505 (1979). Acting as a self-appointed guardian of the government treasury, the Justice Department's Neil Peterson announced that the Swine Flu Act "is not health insur-

ance" and that Congress' "generosity has nothing to do with my paying," thereby breaching the pact between the government and its citizens and betraying the Congressional mandate. Wall St. J., Sept. 15, 1977, at 48.

Petitioner Miriam Stich, together with more than forty million other Americans, responded to her government's call. Within ten days of her inoculation, Mrs. Stich suffered devastating neurological impairment which left her with severe and irreversible physical and intellectual disabilities which require her to be institutionalized for the rest of her life. After the onset of her illness, Mrs. Stich filed a claim under the Swine Flu Act. Rather than conducting an orderly and fair review of her claim, the government declared war on Mrs. Stich. The proceedings below became a showplace in which the Justice Department displayed its full array of adversarial techniques. Armed with superior assets and hidden information, the government played to win, at any cost to Mrs. Stich. *It withheld information and documents, interfered with Petitioners' witnesses, violated court orders, produced surprise expert witnesses, surprise testimony and surprise documents, and announced new theories of defense in the middle of trial.*[1] The government punished the Stichs with its extraordinary abuse of the Federal Rules of Civil Procedure and the Federal Rules of Evidence and its contempt for any semblance of fundamental trial fairness. Although the Justice Department should have held itself to a higher standard of legal

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1. There is a wide discrepancy among the Courts of Appeal regarding control of discovery abuse and particularly regarding the issue of late-emerging expert testimony. The Court of Appeals for the Third Circuit adheres to the minority view that the fairness of a trial is unaffected by the nondisclosure of the identity or testimony of expert witnesses. Trial judges within the Third Circuit have openly complained of their inability to mete out justice in such cases given the state of Third Circuit precedent. See *Certainteed Corporation v. Lexington Insurance Co.*, C.A. No. 82-1668 (E.D. Pa. Dec. 21, 1983). (pp. A-82-A-92).

conduct than that applied to an ordinary attorney, its tactics here would have embarrassed even the shoddiest private practitioner.

If the government is to effectively administer any national immunization program, it must have the trust and cooperation of its citizens. Its conduct before and during the Stich trial violated that trust. Unless this Court requires that the government adhere to its duty to fairly administer claims arising from public health programs, to be open and fair in making available to its citizens public health data collected with public tax money, and to abide by the rules which govern all litigants in federal courts, citizens will be understandably reluctant to participate in government health programs, thus gravely threatening the future of mass public health programs. One need only consider the entire world's concern with health to realize the devastating potential of misguided health programs that have been shielded from review both before and after the fact.

Therefore, this case presents the important issues:

1) Did the Justice Department's harsh, adversarial posture toward Swine Flu Act claimants, characterized in Miriam Stich's case by the suppression of swine flu program data gathered by the Center for Disease Control with public funds, witness interference, repeated violations of federal court orders and denial of procedural safeguards designed to protect her right to effective cross-examination, frustrate the salutary purpose of the Swine Flu Act, violate the government's compact with its citizens and threaten the future effectiveness of vitally important public health programs by undermining the public's confidence in their integrity and fairness, thereby deterring the willing participation of American citizens?

2) Should both private parties and the government be foreclosed at trial from presenting expert testimony which was not previously disclosed to the opposing party, thereby depriving the opposing party of reasonable opportunity to prepare a defense against that testimony?

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## PETITION FOR WRIT OF CERTIORARI

### OPINIONS BELOW

The Opinion of the United States Court of Appeals for the Third Circuit affirming the judgment in favor of defendant is not yet officially reported, and is printed in the Appendix at pp. A-1-A-9.

The Opinion of the United States District Court for the District of New Jersey ordering that judgment be entered in favor of defendant is officially reported at 565 F.Supp. 1096 (D.N.J. 1983), and is printed in the Appendix at pp. A-10-A-64.

## JURISDICTION

The judgment of the United States Court of Appeals for the Third Circuit dated March 19, 1984, was entered on March 19, 1984. (pp. A-66-A-67). The Court of Appeals denied Petitioners' timely Petition for Rehearing En Banc in an Order dated April 23, 1984. (p. A-68). Petitioners invoke the jurisdiction of this Court under and pursuant to 28 U S.C. §1254(1).

## STATUTES INVOLVED

National Swine Flu Immunization Program of 1976, Pub.L.No. 94-380, 90 Stat. 1113, 42 U.S.C. §247b(j)-(l) (1976). This statute is set forth in the Appendix at pp. A-69-A77.

The Federal Tort Claims Act, 28 U.S.C. §§1346(b), 2402, 2671 *et seq.* (1970). The relevant sections of this statute are set forth in the Appendix at pp. A-78-A-80.

Federal Rule of Civil Procedure 26(e). This rule is set forth in the Appendix at p. A-80.

## STATEMENT OF THE CASE

Petitioner Miriam Stich was one of more than forty million Americans who responded in 1976 to the efforts of Respondent, United States of America ("the government") to inoculate the entire population of the country against a perceived threat of a swine flu epidemic. The genesis of the Swine Flu Act, the history of the mass inoculation effort, and the government's effort to persuade individuals to take the shot have been chronicled by numerous courts and commentators and have been the subject of much litigation.[1] *See, Hunt v. United States*, 636 F.2d 580, 589-593 (D.C. Cir. 1980); *McDonald v. United States*, 555 F.Supp. 935 (M.D. Pa. 1983); *Unthank v. United States*, 533 F.Supp. 703, 716-721 (D. Utah 1982); *Bean v. United States*, 533 F.Supp. 567, 571-572 (D. Colo. 1980); Baynes, "Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections On the Swine Flu Experience", 21 St. Louis L.J. 44, 62-69 (1977).

Integral to the implementation of the swine flu program was governmental assumption of liability to inoculation victims injured by the vaccine. To ensure the success of the Program, the federal government directly assumed the liability for injured participants, and disclaimed the "discretionary function" defense available under the Tort Claims Act. In return for this benefit, the government demanded that participating citizens relinquish their right to proceed against third party program

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1. The Swine Flu Program was flawed from the outset. The designers of the plan failed, for example, to even consider the source of the drug industry's insurance problems. As commentators have noted, the Program was characterized by an overconfidence in theories based on little evidence, a reflection of personal agendas, premature decision making, insufficient questioning of scientific logic, and a failure to adequately address uncertainties. R. Newstadt and H. Fineberg, *The Swine Flu Affair: Decision Making On A Slippery Disease* (U.S. HEW pub. 1978) pp. 1-2.

participants, such as the drug manufacturers, and surrender their constitutional right to a trial by jury.[2]

Secure in the knowledge that the government would protect her interests and spurred on by a spectre of a pandemic and calls to patriotism, Mrs. Stich joined millions of other Americans and received her swine flu shot on November 18, 1976. Within ten days of her inoculation, Mrs. Stich suffered devastating neurological impairment which left her with severe and irreversible physical and intellectual impairment. This suit followed.

Mrs. Stich may not have chosen to submit to inoculation if the government had informed her of the potential dangers involved.[3] She certainly would have not submitted if the government had not touted false warnings of an imminent pandemic. Nor would she have made the same decision had she been aware that the Justice Department intended to breach its contractual and statutory duty to fairly compensate innocent victims of the Program.

Unfortunately for Mrs. Stich and hundreds of other swine flu victims, the Justice Department, instead of administering the system to compensate citizens injured by the swine flu inoculation in the "prompt and equitable" fashion required by the statute, retorted that the Swine Flu Act "is not health insurance" and relentlessly

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2. The Swine Flu Act provides that the liability of the United States "may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty." 42 U.S.C. §247b(k)(2)(A)(i). Thus, the Act not only waives the ban against strict liability in tort contained in the federal Tort Claims Act, but also waives the provision of the Tort Claims Act that bars liability "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty . . . whether or not the discretion involved be abused." 42 U.S.C. §247b(k)(2)(A)(ii); 28 U.S.C. §2680(a).

3. The consent form which the government required vaccinees to sign stated in part "[F]lu vaccine has rarely been associated with severe or fatal reactions."

proceeded to engage in fierce litigation. Remarks of Neil Peterson, Wall St. Journal, Sept. 15, 1977 at 48. Mr. Peterson, who headed the Justice Department's administration of swine flu claims, requested $1,228,000 from Congress to finance twenty-eight additional positions and a computer system so that the government would be fully equipped to handle the litigation. As one commentator remarked:

> "Thus, the lawsuits that would otherwise have been aimed at various unconnected private parties are directed by the Swine Flu Act to one arm of the Justice Department, giving it a unique opportunity to concentrate assets and efforts toward a narrow range of cases."

Note, "Statutory Modification and Assumption of Private Liability: The Nuclear Energy and Flu Immunization Programs," 40 U.Pitt.L.Rev. 487, 506 (1979).

Having thus drawn the battlelines, the government proceeded to implement its plan of attack. Of the approximately fifteen hundred cases filed in federal district courts, only a handful were settled in the discovery phase of the litigation. Due to the unwillingness of the government to concede liability, and despite Judge Gessell's[4] efforts to resolve the disputes nationally, the vast majority of cases were some three years later remanded to the transfer court for trial. Rheingold & Shoemaker, "The Swine Flu Litigation," Vol. 8, No. 1, A.B.A. Sec. Litigation at 29 (1981). Thus, Mrs. Stitch and other swine flu victims were subjected not only to the horror of debilitating physical injuries, but also experienced the double tragedy of being forced to fight against their own government.

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4. The Judicial Panel on Multi-district Litigation ordered consolidation of the swine flu cases for pretrial purposes and in early 1977, the cases were assigned to Judge Gerhard Gessell of the District of Columbia.

The Stich suit was remanded to the District of New Jersey on February 5, 1980. Although the government was originally required to respond to Petitioners' Expert Interrogatories by March 13, 1980, at the time of the pretrial conference on July 2, 1980, the government still had not fully answered the interrogatories, nor had it provided any expert reports. Due to the government's failure to meet its discovery obligations, the trial court was forced to postpone the trial from July 14, 1980 to October 1, 1980 and further ordered the government to name its experts and provide expert reports by July 31, 1980. The government failed to comply with that Order. At the request of the government, which pled the illness of an assistant United States Attorney, the trial was again postponed to December 3, 1980.[5] As of that date, the government still had not submitted its Pretrial Memorandum. Ordered by the trial court to do so within 24 hours, the government only then complied and finally filed its Pretrial Memorandum on December 4, 1980.

Beginning in October of 1980, the government used its time to consider and secretly develop a new defense, *i.e.*, that Mrs. Stich's illness was not Guillain Barre Syndrome ("GBS") or post-vaccinal encephalitis which was caused by the swine flu inoculation, but was, rather, a manifestation of Herpes Simplex Encephalitis ("HSE"), an exceedingly rare disease the government contended was unrelated to the inoculation. Interestingly, based upon data from the Center for Disease Control ("CDC"), the government's expert epidemiologist, Dr. Nathanson, later admitted that Mrs. Stich's chances of having independently contracted HSE within nine days of the swine flu shot were less than one in sixteen million.[6]

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5. During the course of the proceedings, three different Assistant United States attorneys conducted the case with little accountability or supervision.

6. Despite the overwhelming odds against it, the trial court found that Mrs. Stich's illness was probably HSE. (p. A-13)

On October 16, 1980, the trial court ordered the government to disclose all experts who reviewed the medical files relevant to Mrs. Stich's case. From November of 1980 to January of 1981, the government secretly had several experts review the Stich file with an eye to the HSE defense. Yet despite the court's Orders, and in violation of the federal rules regarding discovery, the government hid its new defense until the Petitioners had substantially completed presenting their case at trial.

Only then, over two months into the trial, did the government seek leave to add three new experts through whom it planned to present the new HSE defense. Although the trial court found that the government was not only dilatory, but was actually acting in "bad faith", it nevertheless permitted addition of these experts. At the court-imposed deposition of the key surprise witness, Dr. Whitley, in April of 1981, Dr. Whitley asserted that a definitive diagnosis of HSE could not be given without a brain biopsy.

In May of 1981, a mere month after his deposition, Dr. Whitley began writing what he considered to be a trail-blazing article entitled "Herpes Simplex Encephalitis: Clinical Assessment," in which Dr. Whitley formulated a completely new and unproven approach to diagnosing HSE without the necessity of performing a brain biopsy. The article was accepted for publication by the Journal of the American Medical Association in the second week of October, 1981.[7]

Petitioners were never advised by the government that such an article was in progress, that it had been submitted to JAMA, or that it had been accepted for publication. Indeed, the government did not even inform Petitioners of the article's existence until November 2, 1981 when the trial was in progress and Petitioners'

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7. Significantly, the review of the article by the Editorial Board of JAMA found Dr. Whitley's model "insufficient for clinical use." That conclusion is not surprising given Dr. Whitley's publication record of 93 articles in 120 months.

counsel was actively engaged in the courtroom.[8] The following week, during which Petitioners' lawyers were trying the case, Dr. Whitley took the stand on the government's behalf. Even worse, notwithstanding its ongoing obligations under Federal Rule of Civil Procedure 26(e) to advise Petitioners of the change in the substance of the Whitley expert opinion, the government gave Petitioners *no advance notice* that the JAMA article and Dr. Whitley's testimony based on it would completely and drastically change Dr. Whitley's earlier deposition testimony.

The JAMA article formed the centerpiece of Dr. Whitley's trial testimony. He reviewed the analysis contained in his new article at great length and examined its implications for Mrs. Stich's diagnosis. Without the benefit of a brain biopsy or even of having physically examined Mrs. Stich, and in complete contradiction of his deposition testimony, Dr. Whitley asserted that, based on the information contained in his new article, it was at least 85% probable that Mrs. Stich had contracted HSE.

Petitioners objected to Dr. Whitley's trial testimony on the surprise article and moved for leave to examine the data underlying the unpublished JAMA article in order to prepare for Dr. Whitley's cross examination. The court overruled their objection and denied their motion, thus preventing Petitioners from adequately preparing their cross-examination of the government's key wit-

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8. The government engaged in a reoccurring pattern of last-minute document production. In the case of another government expert, Dr. Price, a portion of the scholarly articles on which he relied at trial were given to Petitioners' counsel the night before he was scheduled to testify. The remainder were handed to Petitioners' counsel the morning Dr. Price began his testimony. A "brand new" article on which Dr. Tsairis, another government expert witness, relied was handed to Petitioners' counsel in the midst of Dr. Tsairis' redirect examination.

ness. The Whitley testimony was the key evidence on which the trial court relied in putting Mrs. Stich out of court. In his opinion, the district judge reproduced Table IV from Dr. Whitley's article in its entirety and devoted numerous pages to his adoption of Dr. Whitley's analysis. (pp. A-44-A-60)

Nor was Dr. Whitley the only surprise which the government presented Petitioners. Another expert, Dr. Tsairis, completely repudiated his previous deposition testimony on the witness stand. At his deposition, Dr. Tsairis offered an opinion favorable to Petitioners in two critical respects. First, he testified that Mrs. Stich's symptoms fit the criteria set up by the NINCDS (National Institute of Neurological and Communicative Diseases and Stroke), for the diagnosis of GBS, notwithstanding his personal belief that the criteria were inadequate for diagnosing GBS. Second, he stated that the swine flu shot and a prior influenza vaccine administered to Mrs. Stich on October 25, 1976, together "set off the mechanism that caused an encephalitis"[9] and that "the most probable causation is that the earlier vaccination primed or sensitized her system then the swine flu shot triggered this anamnestic response."

At trial, Dr. Tsairis repudiated both facets of his deposition testimony. He testified that in his opinion, Mrs. Stich did not meet the NINCDS criteria for GBS. At the same time, he discarded his two-shot immunological theory of causation. Instead, to Petitioners' complete surprise, he testified "I don't believe it [the swine flu shot] played any role" in Mrs. Stich's illness. Dr. Tsairis based his change of opinion on the fact that following his deposition, he examined Mrs. Stich and reviewed her actual laboratory data and CAT scans. It was his analysis of the underlying data which caused him, in his words, to

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9. Post vaccinal encephalitis, as well as Guillain Barre Syndrome, is compensable under the Swine Flu Act.

"com[e] out at a different conclusion." In direct violation of F.R.Civ.P. 26(e), Dr. Tsairis' changed opinion was never revealed to Petitioners prior to his actual testimony.

The government further handicapped the Stichs by refusing to produce the underlying data upon which its experts relied. Much of this data had been obtained by the government-operated Center for Disease Control ("CDC") from local health departments across the United States as part of the government's monitoring of the Swine Flu Program. Despite the fact that the CDC data had been collected at citizens' expense to evaluate citizen injuries from the Program,[10] the government repeatedly refused to allow Petitioners to examine the data. Indeed, the CDC declined to honor petitioners' subpoena for the data. Petitioner's further requests to the CDC and the Justice Department to disclose the data were also refused.

The government not only stonewalled Petitioners' efforts to obtain critical information but actively interfered with Petitioners' witnesses. In one instance, the government surreptitiously interviewed Dr. Pertchek, one of Petitioners' expert witnesses, without notifying Petitioners. In another instance, the government improperly barred one of Petitioners' witnesses, Dr. Derby, from testifying, on the pretext that he was a consultant to the Veterans' Administration. Dr. Derby was a critical witness for petitioners. Had he been permitted to testify, he would have asserted that based upon his personal examination of Mrs. Stich and review of her medical records, Mrs. Stich clearly did not have HSE.

In sum, throughout the proceedings, the government disobeyed court orders, and flouted the Federal

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10. The Swine Flu Act imposed a duty on the Secretary of Health, Education and Welfare ("HEW") to conduct and support research on "the nature and effect of the [swine flu] vaccine. . . ." 42 U.S.C. §247b(j)(1)(E). CDC was an HEW agency.

Rules of Civil Procedure and Evidence while marshalling its tremendous assets behind the surprise HSE defense. Far from adhering to the higher standard of conduct expected from the Justice Department, the government's conduct here went beyond "sharp" practice to the dark side of unethical tactics.

The conduct of the Justice Department during this swine flu litigation sets a dangerous precedent for future public health programs. Effective mass immunization programs depend upon the cooperation of the nation's citizens. The lesson learned by the Stichs and millions of other citizens from the Swine Flu affair is that the government cannot be trusted. In handling the administration of swine flu claims, the Justice Department breached the government's contract with its citizens, repudiated the Congressional mandate and betrayed the trust of both Congress and the swine flu victims. Unless this Court requires that the government honor its contract with its citizens and fulfill its statutory mandate under the Swine Flu Act, citizens will be understandably reluctant to submit to government requests and the future of mass inoculation programs and the nation's health will be severely jeopardized.[11]

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11. Governmental involvement in public health programs will inevitably continue. Alarmed by the high drop-out rate of large drug companies engaged in vaccine production, the Institute of Medicine of the National Academy of Sciences is presently conducting a study of the reasons why companies are unwilling to engage in vaccine production. The American Medical Association recently approved a report "calling for the Federal Government to assume responsibility for compensating the victims of mandatory childhood immunization programs, relieving the manufacturers of liability risk unless they are negligent." Concerned with the shrinking supply of vaccines, U.S. Senator Paula Hawkins and U.S. Representative Henry Waxman have introduced legislation to establish a federal system of compensating those injured by vaccines. (N.Y. Times, "Vaccine Liability Threatens Supplies," June 26, 1984, p. C1).

## REASONS FOR GRANTING THE WRIT

### A. The Government's Conduct In The Proceedings Below Violated Its Statutory Duty To Fairly Administer Claims Arising Under The Swine Flu Act And To Comport Itself According To The Standards Required Of All Attorneys

The government's handling of petitioners' claim both prior to and throughout the proceedings below violated its compact with its citizens and its statutory duty to fairly, efficiently and equitably administer claims arising under the Swine Flu Act as well as its duty to litigate ethically and according to the standards required of government attorneys.

In persuading its citizens to participate in the mass inoculations, the government essentially made a pact with the participating citizen. In exchange for the citizen's submission to inoculation, the government agreed to accept liability for any injury resulting therefrom. Both the citizen and the government were bound by this contract. "The consent form procedures may be received as tacit recognition of this conceptualization by Congress, the inoculee's signature serving to memorialize the contract." *Wolfe v. Merrill National Laboratories, Inc.*, 433 F.Supp. 231, 237 (M.D. Tenn. 1977).

The Swine Flu Act itself explicitly defines the duty owed by the government to its citizens under this pact. The Act requires the government to do more than merely develop safe and effective vaccines and procedures and to fully disclose the risks and benefits of the vaccine to each participant. 42 U.S.C. §247b(j)(1)(A) and (F). The Act also required procedures which would advise "individuals with respect to their rights and remedies arising out of the administration of such vaccine." 42 U.S.C. §247b(j)(l)(F). Recognizing that it had a duty to fairly treat and protect recipients of vaccines, Congress set up a system which was to assure an "orderly proce-

dure for the *prompt and equitable* handling of claims" by persons alleging injuries or death as a result of the vaccine. 42 U.S.C. §247b(k)(1)(A)(ii) and §247b(k)(1)(B)(i). (Emphasis added.) Further recognizing its duty to fairly treat citizens who heeded the government's urgent call for participation in the program, Congress provided in the Act for the relaxation of the previously strict requirement that a claimant file an administrative claim within a certain limited time period before suing. 42 U.S.C. §247b(k)(2)(A)(iii). Further, the procedure provided for dispute resolution was only to be a temporary measure "until Congress develops a permanent approach for handling claims." 42 U.S.C. §247b(k)(1)(A)(iii). This idea — that the federal government had a continuing obligation to use the most equitable method of handling claims — is further supported by the requirement that the Secretary of Health, Education and Welfare "conduct . . . a study of . . . alternative approaches . . . (including a compensation system) for such injuries." Act of Aug. 12, 1976, P.L. 94-380,§3,90 Stat. 1118. On its face, the Swine Flu Act obligates the government to fairly, efficiently and equitably handle claims resulting from the Swine Flu Program.

Clearly, the government's conduct during the Stich proceedings grossly violated this duty. It is beyond dispute that the government is bound, as are private litigants, to comply with the Federal Rules of Civil Procedure regarding discovery. *United States v. Procter & Gamble*, 356 U.S. 677 (1958). As stated previously, the Government refused to fully answer expert interrogatories in a timely fashion; refused to furnish expert reports and identify experts; refused to comply with various court orders; added new experts; added a new defense after the Petitioners had substantially completed their trial presentation; violated its Rule 26(e) duty to supplement earlier discovery responses and thereby knowingly concealed information which made prior responses incorrect; refused to furnish underlying data

which would allow effective cross-examination of various government witnesses; refused to comply with subpoenas; and actively interfered with Petitioners' witnesses. Such behavior on the part of a private litigant would be reprehensible. What is even more shocking is that the party which violated and showed such flagrant disregard for these rules is the United States Government, and that the government's behavior occurred in a highly complex case in which the government had become an adversary of the citizens it was duty-bound to protect. Rheingold & Shoemaker, "The Swine Flu Litigation", Vol. 8-No. 1 A.B.A. Sec. *Litigation* 28 at 50 (1981).[12]

Just as when considering the issue of sanctions a court must take into account the symbolic and actual effect on other parties in different suits (*National Hockey League v. Metropolitan Hockey Club, Inc.*, 427 U.S. 639 (1976)), so too must this Court consider the effect of approving the government's conduct here. Such approval would send a loud and clear signal that the Federal Rules of Civil Procedure do not apply to the government.

Some sixty-four years ago Justice Holmes wrote that "[m]en must turn square corners when they deal with the government." *Rock Island, Arkansas & Louisiana Railroad Co. v. United States*, 254 U.S. 141, 143 (1920). Justice Jackson's response that "It is very well to say that those who deal with the Government should turn square corners. But there is no reason why the square corners should constitute a one way street" (*Fed-*

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12. The Federal Rules of Civil Procedure, of course, were intended to eliminate surprise and facilitate the search for the truth. See, for example, C. Wright, *The Law of Federal Courts* at 540 (4th ed. 1983) and Advisory Committee Notes to F.R.C.P. 26. In such a highly complex case as this, it is inconceivable that Petitioners would be denied access to important data in the government's possession on the basis that they would not be unduly prejudiced when the government based its defense on that same data.

*eral Crop Insurance Corp. v. Merrill*, 332 U.S. 380, 387-388 (1947) (dissent), explains many of the practices and rules in criminal, administrative and civil proceedings. Nineteen years ago, this Court declared that a fair trial was this country's constitutional goal. *Pointer v. Texas*, 380 U.S. 400 (1965). Various courts and commentators have noted that the integrity of the criminal justice system and public confidence in the system depend on full disclosure of all facts needed either by prosecution or defense within the framework of the rules of evidence. *United States v. Nixon*, 418 U.S. 683, 709 (1974). The Jencks Act, 18 U.S.C. §3500, is just one example of this concept which has been embraced in proceedings before administrative agencies ranging from the N.L.R.B. to the Department of Justice. *Harvey Aluminum Inc. v. N.L.R.B.*, 335 F.2d 749, 754 (9th Cir. 1964). "The laws under which these agencies operate prescribe the fundamentals of fair play." *Harvey Aluminum Inc. v. N.L.R.B.*, 335 F.2d 749, 753, and *Federal Communications Commission v. Pottsville Broadcasting Co.*, 309 U.S. 134, 143-144 (1940).

"It is the duty of the government to present its case . . . fairly." *United States v. Baum*, 482 F.2d 1325, 1332 (2d Cir. 1973). In every case in which a United States Attorney is involved, that attorney "represents the great authority of the United States and he must exercise that responsibility with the circumspection and dignity that the occasion calls for." *United States v. LeFevre*, 483 F.2d 477, 478 (3d Cir. 1973).

The conduct of the government both before and during trial not only violated its duty to fairly, efficiently, and equitably handle the permanently injured Petitioner's claim and its duty to comply with the Federal Rules of Civil Procedure but also offends that principle which is inscribed on the walls of the Department of Justice: "The United States wins its point whenever justice is done its citizens in the courts." *See Brady v. Maryland*, 373 U.S. 83, 87 (1963).

### B. There Is A Conflict Among The Circuits Regarding The Issue Of Late Emerging Expert Testimony

In the instant case, the Third Circuit Court of Appeals adhered to the policies expressed by it in *Meyers v. Pennypack Woods Home Ownership Ass'n.*, 559 F.2d 894 (3d Cir. 1977) where it reversed a trial court for excluding at trial the testimony of two fact witnesses identified shortly before trial. The lack of definite guidance concerning the admissibility of late-emerging expert testimony has seriously interfered with the ability of the trial judges in the Third Circuit to manage a case effectively, and has been openly criticized by trial judges in that Circuit. Commenting on the tactics of counsel who, in four separate cases within the course of a single month, had failed to identify experts until after the court's discovery deadlines had passed, District Judge Van Artsdalen of the Eastern District of Pennsylvania observed that "this increasingly serious problem in the smooth administration of justice" (p. A-84) was attributable to the Third Circuit's unintentional encouragement of such conduct in its post-*Pennypack Woods* decisions. *Certainteed Corp. v. Lexington Ins., Co.*, C.A. No. 82-1668 (E.D. Pa. Dec. 21, 1983). In reviewing the relevant decisions of the Third Circuit, Judge Van Artsdalen found that his "[r]esearch discloses that there is not a single reported case in this circuit where a district judge's exclusion of a key fact witness or expert witness was upheld." (p. A-85).

In contrast, the Second, Fifth, Eighth and Tenth Circuits have taken affirmative action to curtail the use of what one commentator[13] has dubbed "Saturday Night" experts. *See, Smith v. Ford Motor Co.*, 626 F.2d 784, 791-800 (10th Cir. 1980), *cert. denied*, 450 U.S. 918 (1981) (judgment for plaintiff reversed where trial

13. Graham, "Discovery of Experts Under Rule 26(b)(4) of the Federal Rules of Civil Procedure: Part Two: An Empirical Study and Proposal," 1977 U. Ill. L. Forum 169, 187.

testimony of plaintiff's expert exceeded the scope of his testimony as described in pretrial submission; court noted that the duty to supplement expert interrogatories continues through trial); *Shelak v. White Motor Co.*, 581 F.2d 1155, 1158-59 & n.4 (5th Cir. 1978) (judgment for plaintiff reversed where plaintiff failed to supplement answers to expert discovery as required by Rule 26(e), thereby depriving defendant of reasonable opportunity to defend against new contention unveiled five or six days prior to trial); *Voegeli v. Lewis*, 568 F.2d 89, 96 (8th Cir. 1977) (judgment for defendant reversed where defendant neglected its obligations under Rule 26(e) and failed to reveal that expert had changed his opinion since his deposition); *Weiss v. Chrysler Motor Corp.*, 515 F.2d 449 (2d Cir. 1975) (judgment for defendant reversed when defendant's expert, in violation of Rule 26(e), based his opinion on previously undisclosed test). *See also, Port Terminal & Warehousing Co. v. John S. James Co.*, 695 F.2d 1328, 1335 (11th Cir. 1983) (neglecting to supplement outstanding interrogatories with experts' names before close of discovery is inexcusable). The conflict among the Circuits should be resolved by the Court to ensure that a litigant who must cross-examine a hostile expert witness will have the necessary discovery tools and adequate time, in advance of the expert's appearance on the stand, to probe the basis of the expert's opinion. If the instant decision remains the law in the Third Circuit, trial judges will face the situation which the Fifth Circuit deplored when it stated;

> "There was a day when litigants learned their opponents' contentions during trial. That day is said to have ended. . . . Affirmance of this case would authorize its return."

*Shelak v. White Motors Co.*, 581 F.2d 1155 at 1160 (5th Cir. 1978).

## CONCLUSION

For the foregoing reasons, a writ of certiorari should issue to the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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# APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 83-5343

---

ERNEST STICH and MIRIAM STICH
*Appellants*

v.

UNITED STATES OF AMERICA

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Appeal From the United States
District Court For the
District of New Jersey - Trenton

D.C. Civil No. 78-0746

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Argued January 24, 1984

Before: HUNTER, WEIS, *Circuit Judges*,
and DUMBAULD,* *District Judge*

Opinion filed March 19, 1984

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Robert P. Casey (Argued)
Constance B. Foster
Alexandra D. Sandler
Dilworth, Paxson, Kalish
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*Honorable Edward Dumbauld, United States District Judge for the Western District of Pennsylvania, sitting by designation.

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**OPINION OF THE COURT**

HUNTER, *Circuit Judge:*

1. This case arose from the campaign of the United States to inoculate its population against the Swine Influenza virus. Nine days after receiving a Swine Flu vaccination, Miriam Stich ("Mrs. Stich") became seriously ill. Claiming that she had contracted Guillian-Barre Syndrome ("GBS") or some other disease causally related to the Swine Flu shot, Mr. and Mrs. Stich filed suit against the United States. The United States argued that Mrs. Stich suffered from Herpes Simplex Encephalitis ("HSE"), a disease believed to be unrelated to Swine Flu vaccinations. After a lengthy and complex bench trial, the district court held that plaintiffs had not sustained their burden of proving that Mrs. Stich contracted GBS or some other disease caused by the Swine Flu shot, and entered judgment in favor of the United States. Plaintiffs appeal on a number of grounds. We find no error in

the trial court proceedings, and will affirm the judgment of the district court.

I.

2. Mrs. Stich received a Swine Flu shot on November 18, 1976. On November 22, 1976 she began to feel ill, suffering from a fever, muscle aches, a headache and general malaise. The family physician, Dr. Joseph Gluck, saw Mrs. Stich at home on November 26th. Although she felt quite unwell, the physical examination revealed nothing remarkable. Dr. Gluck prescribed rest and aspirin.

3. On November 27, 1976, Mrs. Stich's condition took a dramatic turn for the worse. She was admitted to the Emergency Room of Riverview Hospital in New Jersey completely unconscious, with convulsions and a fever. During her convulsive state, Dr. Gluck noted that Mrs. Stich showed physical signs of decerebration. Dr. Gluck diagnosed the problem as meningoencelphalitis of unknown etiology.

4. For the next three or four days, Mrs. Stich's level of consciousness varied substantially, although she never completely recovered. By December 2, 1976, she was totally unconscious and unresponsive, and she remained comatose or semi-comatose for the next three to four months.

5. On February 14, 1977, Mrs. Stich was transferred to the Neurological Institute at Columbia Presbyterian Hospital in New York City. During her stay there, her vital signs were stable and normal. Although she did not respond to external stimuli, she did occasionally open her eyes and look around her room. No verbalization took place.

6. Mrs. Stich was returned to Riverview Hospital, where she currently remains, on March 8, 1977. As a result of intensive therapy, Mrs. Stich eventually became able to walk with substantial assistance, to feed herself occasionally, and to perform certain other activities of

daily living. She remains seriously disoriented, however, and much of her speech is unintelligible. On October 14, 1981 a physical examination revealed that Mrs. Stich was spastic in all four extremities, and continued to exhibit bilateral Babinski reflexes. She could not follow objects or fingers with her eyes, suffered a mild ptosis (drooping of the eyelid), and would attempt to put into her mouth any object coming into her visual field. In sum, Mrs. Stich's residual intellectual impairment is substantial.

II.

7. On April 12, 1978, pursuant to the Federal Tort Claims Act, 28 U.S.C. §§2671-2680 (1976), and the Swine Flu Act, 42 U.S.C. §247b(k) (1976), Mr. and Mrs. Stich filed suit against the United States in the United States District Court of New Jersey. Plaintiffs contended that Mrs. Stich had contracted either GBS or some other condition as a result of Swine Flu Innoculation. The United States contended that Mrs. Stich's illness was not caused by the Swine Flu shot and that she suffered a viral ancephalitis, probably HSE, unrelated to the flu vaccine.

8. Plaintiffs' action was transferred by the Judicial Panel on Multi-District Litigation to the United States District Court for the District of Columbia for the coordinated and consolidated pre-trial proceedings pursuant to 28 U.S.C. §1407 (1976). *See In Re Swine Flu Immunization Products Liability Litigation*, MDL-330 Misc. No. 78-0040 (D.D.C.). On February 5, 1980, plaintiffs' action was remanded to the New Jersey court for a trifurcated trial.[1] The final pre-trial order of the District of Columbia court provided that plaintiffs estab-

1. It was contemplated that the diagnosis and causation of Mrs. Stich's condition would be determined in Phase I; Phase II would deal with foreseeability of risk and informed consent; and Phase III would determine damages. Phases II and III proved to be unnecessary in this case.

lished that Mrs. Stich had contracted GBS, liability would be conclusively presumed. If however, a disease other than GBS were established, plaintiffs would need to prove negligence or some other appropriate theory of liability.

9. The trial court found that plaintiffs had failed to establish by a preponderance of the evidence that Mrs. Stich suffered from GBS or any other condition causally related to the Swine Flu Innoculation. Rather, it concluded, Mrs. Stich suffered from HSE.

10. Plaintiffs appeal on a variety of grounds,[2] only one of which requires discussion. Plaintiffs argue that they were unfairly surprised when they received an article[3] only one week before its author, government expert Dr. Whitley, was scheduled to testify. Therefore, they argue, either Dr. Whitley should have been prevented from relying on the new article and the Government should have been prevented from using it at all, or plaintiffs should have been allowed to examine the article's underlying data so that they could effectively cross-examine Dr. Whitley.

11. In arguing that the trial judge abused his discretion in overruling their objections to the use of the article and in denying their request for leave to inspect the

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2. Plaintiffs argue that the trial court's findings that Mrs. Stich did not contract GBS or another neurologic condition causally related to the Swine Flu shot were clearly erroneous, that the trial court abused its discretion by permitting the government to present the testimony of certain expert witnesses and denying plaintiffs access to the data relied upon by those experts, by denying plaintiffs' request to depose certain consultants employed by the United States, and by failing to permit a doctor employed by the United States to testify for the plaintiffs. Finally, plaintiffs argue that the trial court's decision-making process was impaired because the United States improperly wrote to the court during deliberations. We have carefully considered all of these contentions, and have concluded that they are meritless.

3. Whitley, et al., "Herpes Simplex Encephalitis: Clinical Assessment," JAMA 247:317-320 (Jan. 15, 1982.)

underlying date, plaintiffs have a heavy burden to bear. In general, the conduct of trial is left to the broad discretion of the trial judge, and the court of appeals will not retroactively substitute its judgment for that of the trial judge unless there has been an abuse of discretion. *See, e.g. Excel Handbag Co. v. Edison Brothers Stores, Inc.*, 630 F.2d 379, 388 (5th Cir. 1980); *Dobson v. Bacon Transport Co.*, 607 F.2d 805, 807 (8th Cir. 1979); *Rasmussen Drilling, Inc. v. Kerr-McGee Nuclear Corp.*, 571 F.2d 1144, 1154-55 (10th Cir.), *cert. denied*, 439 U.S. 862 (1978). This general rule is applicable to the matter of the admission or exclusion of expert evidence. *See, e.g., Seese v. Volkswagenwerk A.G.*, 648 F.2d 833, 844 (3d Cir.), *cert. denied*, 454 U.S. 867 (1981); *Fuentes v. Reilly*, 590 F.2d 509, 511 (3d Cir. 1979).

12. Plaintiffs attempt to bolster their argument by claiming a right to the data under the rules of discovery. Plaintiffs' reliance on the rules of discovery does not help them, however, because the conduct of discovery is also committed to the sound discretion of the district court. *In re Fine Paper Antitrust Litigation*, 685 F.2d 810, 817 (3d Cir. 1982), *cert. denied sub nom. Alaska v. Boise Cascade Corp.*, 103 S. Ct. 801 (1983). The substantial discretion granted to trial courts on discovery motions should not be lightly disturbed, *Imperial Ethiopian Government v. Baruch-Foster Corp.*, 535 F.2d 334, 337 n.8 (5th Cir. 1976), even if the reviewing court's notions of fairness would have led it to a different result. *Mendoza v. Tucson School District No. 1*, 623 F.2d 1338, 1347 (9th Cir. 1980), *cert. denied sub nom. Sanchez v Tucson Unified School District No. 1*, 450 U.S. 912 (1981).

13. To show an abuse of discretion under either theory, appellants must show that the trial court's action was " 'arbitrary, fanciful or clearly unreasonable.' " *Marine Petroleum Co. v. Champlin Petroleum Co.*, 641 F.2d 984, 991 (D.C. Cir. 1979) (citation omitted). Otherwise stated, they must show that "no reasonable person could concur in the trial court's assessment of the issue under

consideration." *Locascio v. Teletype Corp.*, 694 F.2d 497, 499 (7th Cir. 1982), *cert. denied*, 103 S. Ct. 1876 (1983). Appellants have failed to make such a showing in this case.

14. The discovery request presented, as the trial court aptly termed it, "a close case." One can readily appreciate the plaintiffs' position when they were presented with a new — and potentially quite damaging — article one week before a government expert was scheduled to testify. On the other hand, there is no serious contention that the United States actually concealed the article; Dr. Whitley simply did not finish it until shortly before he was scheduled to testify. Furthermore, the plaintiffs' claim of surprise is attenuated by the fact that they had long been aware of several acticles written by Dr. Whitley that relied on essentially the same data base,[4] but had not requested discovery of that data. Finally, the court's concern that granting plaintiffs' request would unduly delay the trial was hardly unreasonable. It was also a problem which plaintiffs did nothing to mitigate. Although plaintiffs had had the new article for a week before Dr. Whitley was scheduled to testify, they waited until Dr. Whitley was on the stand and testifying to make their discovery request. It is true that this trial was later adjourned and that affording plaintiffs access to the requested data might not actually have delayed the trial. Discovery rulings, however, cannot be judged by the standards of what hindsight has revealed. At the time the trial judge was making the decision, it was not an abuse of discretion to conclude that plaintiffs'

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4. Plaintiffs were aware at Dr. Whitley's April 1981 deposition of various Study Group articles on the issue of predicting the HSE diagnosis including: "Adenine Arabinoside Therapy of Biopsy-Proved HSE," N.E.J. Med. 297:289-294 (Aug. 1977): "HSE: Need for Accurate Diagnosis," MAMA 244:371-372 (July 25, 1980); "HSE: Vidarabine Therapy and Diagnostic Problems," N.E.J. Med. 304:313-318 (Feb. 5, 1981); and "Diagnosis and Treatment of Herpes Simplex Encephalitis," Ann. Rev. Med. 32:335-340 (1981).

need for discovery was not so great as to warrant yet another lengthy delay of the trial.[5]

15. Likewise, after concluding that plaintiffs could adequately prepare to cross-examine Dr. Whitley from already available data, it was not an abuse of discretion to allow Dr. Whitley to rely on the article in testifying. As this court pointed out in *Rovegno v. Geppert Brothers Inc.*, 667 F.2d 327 (3rd Cir. 1982), particular deference is due to a trial judge's decisions weighing the relevancy of evidence against the possibility of unfair prejudice "because of [the trial judge's] superior position from which to assess the extent of potentially unfair prejudice. He, not the appellate judge, has the totality of evidence before him, [citation omitted] and must respond to evidentiary questions as they arise. Therefore, a reviewing court should be hesitant to substitute its own analysis based on a cold record."[6] *Id.* at 330.

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5. The trial judge appeared to decide this motion under Rule 403 of the Federal Rules of Evidence. Clearly, this evidentiary rule had no bearing on plaintiffs' discovery request, and to the extent that the court and government counsel relied on it regarding plaintiffs' discovery motion, both were confused. We are not, however, persuaded that this confusion requires a different result. In this case, whether the court believed its balancing to be an exercise under Rule 403 or simply a part of making discovery decisions, the interests to be balanced were the same. Plaintiffs were not prejudiced by the district court's use of the wrong label. *Cf. Santos v. Immigration & Naturalization Service*, 375 F.2d 262, 264 (9th Cir. 1967) (if sufficient reason for exercise of discretion exists, ill-advised reason may be disregarded as surplusage).

6. In addition, we note that a fair reading of the district court's opinion suggests that the judge did not rely on Dr. Whitley's article or testimony in deciding that Mrs. Stich did not have GBS: he so decided because he concluded that she did not exhibit the symptoms necessary to a diagnosis of GBS. It appears that the judge relied on the contested article and testimony only in concluding that Mrs. Stich had HSE — a conclusion unnecessary to the judge's decision that plaintiffs failed to carry their burden of proving that Mrs. Stich's illness was caused by the Swine Flu shot. Because we have concluded that the admission of this article was not an abuse of discretion, however, we need not rely upon this observation in deciding this case.

16. On appeal, plaintiffs also argue that, under Rule 1006 of the Federal Rules of Evidence, they had an absolute right to discover the data underlying "Table 4" of the article. Therefore, they claim, the trial court erred in admitting Table 4 into evidence and in allowing Dr. Whitley to rely on it in his oral testimony without granting them access to the underlying data. While there is some force to this argument, we find that plaintiffs waived it by failing to raise it below in a specific and timely fashion.

17. Plaintiffs did not object at the time that Table 4 was received into evidence. Such an objection would not have been "futile," as plaintiffs contend. Although plaintiffs had previously argued their right to examine the data underlying Dr. Whitley's article, they never argued that they had a separate right to the data underlying Table 4. Indeed, they never requested the data underlying Table 4 separately from the data underlying the article as a whole. That difference is significant. Plaintiffs' objection to admitting Dr. Whitley's testimony without allowing them to examine the data upon which he relied was predicated on a balancing of prejudice and unfair surprise against materiality and delay in the litigation. Plaintiffs' present objection, based on Rule 1006, invokes a purported absolute right to probe the bases for a "chart, summary or compilation." In the absence of any timely, specific objection, we cannot predicate any error on the admission into evidence of Table 4. Fed. R. Evid. 103(a)(1).

18. Because we conclude that the district court neither erred as a matter of law nor abused its discretion, we will affirm the judgment below.

A True Copy:
Teste:

*Clerk of the United States Court of Appeals*
*for the Third Circuit*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ERNEST STICH and MIRIAM STICH,
*Plaintiffs*

*v.*

UNITED STATES OF AMERICA,
*Defendant*

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(Civil Action No. 78-746)
Before: ACKERMAN, *District Judge*
Filed February 8, 1983

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**OPINION**

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This is an action brought pursuant to the Federal Tort Claims Act, 28 U.S.C. §2671, *et seq.*, and the Swine Flu Act, 42 U.S.C. §47(b). Plaintiffs, Mrs. Miriam and Dr. Ernest Stich, seek to recover damages allegedly suffered as a result of a swine flu inoculation which Mrs. Stich received on November 18, 1976, pursuant to the national immunization program undertaken by the federal government. *See* The National Swine Flu Immunization Program of 1976, Pub.L. 94-380, 90 Stat. 1113. Specifically, Mrs. Stich contends that she contracted either Guillain-Barre Syndrome ("GBS") or some other condition as a result of this immunization which, in turn, caused her to suffer her injuries. Her husband, Dr. Stich, seeks recovery for loss of consortium and loss of services.

Under the Federal Tort Claims Act, as incorporated in the Swine Flu Immunization Act, this action is governed by the law of the forum state, here New Jersey, except as otherwise provided. 28 U.S.C. §1346(b); 42 U.S.C. §247b(k)(2)(A); *Richards v. United States*, 369 U.S. 1 (1962).

## PROCEDURAL HISTORY

This action was filed on April 12, 1978. On May 18, 1978, it was transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the District of Columbia for coordinated and consolidated pretrial proceedings pursuant to 28 U.S.C. §1407 before the Honorable Gerhard A. Gesell. The case was thereafter remanded to this court on February 5, 1980. The Final Pretrial Order of the transferee court, dated November 15, 1979, provides that if plaintiffs establish that Mrs. Stich contracted GBS, they need not establish any theory of liability. If, however, it cannot be established that she has GBS, then plaintiffs must prove negligence or another appropriate theory of liability.

The Final Pretrial Order also limits the litigants herein to local discovery, meaning only that which is specifically related to her condition. Over seventy depositions were taken during the course of national discovery, many of which were introduced into evidence at trial in this action.

The trial of this nonjury case was trifurcated. The three phases contemplated in the pretrial order are: Phase I—Diagnosis and Causation of Miriam Stich's condition; Phase II—Foreseeability of Risk and Informed Consent; Phase III—Damages. After thirty-nine days of testimony comprising some 6,390 pages of trial transcript, the trial of Phase I has been completed. The plaintiffs have presented medical testimony through the following witnesses:

Dr. Joseph Gluck, internist and a treating physician of Mrs Stich

Dr. Howard Medinets, neurosurgeon and specialist in forensic medicine

Dr. Robert Lisak, neurologist

Dr. Charles Poser

Plaintiffs also presented testimony by deposition of certain doctors drawn from the Multi-district discovery proceedings in the consolidated swine flu cases. *See In re Swine Flu Immunization Products Liability Litigation*, MDL No. 330, Misc. No. 78-0040 (D.C.D.C.).

The United States presented medical evidence through the following witnesses:

Dr. Peter Tsairis, neurologist and electromyographer

Dr. Richard Price, neurologist and virologist

Dr. Richard Whitley, virologist and Director of the National Institute of Allergy and Infectious Diseases ("NIAID") Collaborative Anti-Viral Study Group

Dr. Neal Nathanson, epidemiologist and microbiologist

Defendants also presented testimony through the Multidistrict depositions, including the following witnesses:

> Dr. Barry Arnason, Dr. Paul Wehrle, Dr. Stephen Schoenbaum, Dr. Peter Dyck, Dr. Larry Schonberger, Dr. Henry Retailliau, Dr. Alexander Langmuir, Dr. Jonas Salk, Dr. Frederick Davenport, Dr. Harry Meyer, Dr. David Karzon, Dr. Gordon Meiklejohn, Dr. D.A. Henderson. Dr. David Sencer, Dr. Charles Hoke, Dr. J. Donald Millar, Dr. John Seal, and Dr. E. Russell Alexander.

The court has carefully considered the live testimony, the deposition testimony, the exhibits submitted, and the arguments of counsel. This memorandum constitutes the court's decision and includes the court's findings of fact and conclusions of law pursuant to Federal Rules of Civil Procedure 52(a). I find that Mrs. Stich has failed to establish by a preponderance of the credible evidence that the condition she is suffering from is GBS, or that it is causally related to the swine flu inoculation which she received. I find instead that the most probable diagnosis of Mrs. Stich's condition is herpes simplex encephalitis ("HSE") of a viral etiology unrelated to the swine flu inoculation she received. *See Caputo v. United States*, 157 F.Supp. 568, 571 (D.N.J. 1957); *Szczytko v. Public Service Coordinated Transport*, 21 N.J. Super 258, 264 (App. Div. 1952).

## MRS. STICH'S MEDICAL HISTORY

It is undisputed that Mrs. Stich received a swine flu inoculation at Brookdale Community College on November 18, 1976.[1] That afternoon she flew to California on a pleasure trip, where she stayed for five days. On November 22, 1976, towards the end of her stay in California,

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1. Mrs. Stich received only one other inoculation in the one year period prior to her swine flu inoculation on this date, a flu vaccine type B, on October 25, 1976.

she began to feel ill. She returned home to New Jersey the next day. At that time she had a fever, muscle aches, a headache and noted a general malaise. Her physician husband put her to bed and gave her Keflex and aspirin. The following day, November 24, 1976, she remained ill with a fever of 102 degrees and was in bed, and on November 25, 1976, she was not well enough to prepare the Thanksgiving dinner.

On November 26, 1976, Mrs. Stich was seen at her home by the family's physician, Dr. Joseph Gluck. Although she still had a fever and complained of a headache and a general loss of well-being, her physical examination at that time was otherwise unremarkable. Her urinalysis and complete blood count were normal, and Dr. Gluck prescribed rest and aspirin.

On November 27, 1976, Mrs. Stich was taken to the Emergency Room of Riverview Hospital in Red Bank, New Jersey, where she was admitted at 12:00 p.m. Upon examining Mrs. Stich, Dr. Gluck found her condition dramatically changed. He noted that she now had convulsions as well as a fever. She was totally unconscious, and the muscles of all her extremities were in spasm. Her neck was supple, her eyes were roving horizontally without focusing, although they were deviating mainly to the left. Her pupils were equal, small and reacted normally to light. The Babinski and Hoffman reflexes, which are indicative of CNS pathology, were both abnormal. Mrs. Stich appeared to have normal power in her extremities and she was continent. During her convulsive state, Dr. Gluck noted that Mrs. Stich showed physical signs of decrebration. The family history, which was taken on November 27, 1976 and dictated by Dr. Gluck, indicates the following:

> Examination in the past has been without any significant abnormalities other than residual polio affecting both lower extremities, mainly to the left; approximately five days ago, while in California, she

> noted the onset of malaise, muscle aches, headache and then fever. She flew home and by the next day, had temperature to 102 degrees with marked loss of well-being. There were no other specific symptoms. The illness had the character of a typical acute febrile viral infection.

Diagnosis on admission by Dr. Gluck was meningo-encephalitis of unknown etiology. Dr. Gluck was unaware until December 10, 1976, that Mrs. Stich had received a swine flu inoculation on November 18, 1976. Dr. Gluck had, however, himself given her an influenza B inoculation on October 25, 1976.

For the three or four days following her admission to Riverview Hospital, Mrs. Stich's level of consciousness varied substantially, although she never regained full normality. By December 2, 1976, she was totally unconscious and unresponsive, and she remained comatose or semi-comatose for the next three to four months.

On February 14, 1976, Mrs. Stich was transferred to the Neurological Institute at Columbia Presbyterian Hospital in New York, New York. This transfer was apparently made for the purpose of seeking assistance with the diagnosis treatment of Mrs. Stich's condition, and perhaps to facilitate the performance of a brain biopsy. The medical records from her stay at Columbia Presbyterian Hospital indicate that during this period her vital signs were stable and normal. Although she did not respond to external stimuli, she did occasionally open her eyes and look around her room. No verbalization took place.

On March 8, 1977, she was again re-hospitalized at Riverview Hospital. By April or May her coma had lightened to the point that she was awake. On June 6, 1978, she was transferred to Morris Hall Rehabilitation Center and remained there until August 15, 1978, when she was again returned to Riverview Hospital. Mrs. Stich currently remains at Riverview.

As a result of intensive therapy, Mrs. Stich eventually became able to walk with substantial assistance, sometimes feed herself and perform certain other activities of daily living. She remains seriously disoriented, however, and much of her speech is unintelligible. Aphysical examination by Dr. Tsairis on October 14, 1981, found her spastic in all four extremities. She still exhibited bilateral Babinski reflexes, and could not follow objects or fingers with her eyes. She had a mild left ptosis (drooping of the eyelid) and would attempt to put into her mouth any object that would come into her visual field. As is clear from this summary, Mrs. Stich's residual intellectual impairment is substantial.

## GUILLIAN-BARRE SYNDROME - GBS

Guillian-Barre Syndrome is a neurologic disorder, inflammatory in nature, which was first described in 1859 by Dr. Landry. It was again described in 1916 by Drs. Guillian, Barre and Stohl. The syndrome characterizes a set of neurologic symptoms, rather than defining a specific organic disorder. To date, medical science has not established the syndrome's exact etiology or cause.

The extent to which GBS may encompass any central nervous system ("CNS") involvement remains a controversy within the medical community. As classically defined, GBS is a peripheral neuropathy which results from the demyelination of the peripheral nervous system.[2] This demyelination results in a progressive motor weakness of the limbs which ranges from mild weakness to paralysis of every motor muscle. Most typically GBS involves the lower extremities initially, progressing (normally over the course of between a few days and two weeks) upward to affect the upper limbs, face and bul-

2. The peripheral nervous system includes the nerves which extend away from the brain, the brain stem, and the spinal cord. The central nervous system consists of the brain, brain stem and the spinal cord.

bar muscles. This progressive weakness affects both proximal and distal muscles, and it reaches a plateau in the second or third week after onset as the affected muscles begin to re-myelinate. Over the course of a period ranging from three months to one year, GBS patients generally regain full use of the affected muscles, although there are permanent residual effects in approximately 10% of all GBS cases.

Plaintiffs urge this court to adopt a much broader clinical definition of GBS. Their position is that GBS may embrace a wider spectrum of neurologic or CNS involvement than suggested by the classical definition, and that GBS does not represent any specific neurologic picture. They argue that GBS properly includes central nervous system disease as well as peripheral nervous system disease, and may affect any or all, or any combination of the parts, of the nervous system.

## THE "NINCDS" CRITERIA

While the precise nature of the syndrome may be in dispute, the criteria established for the diagnosis of GBS by the National Institute of Neurological and Communicative Diseases and Stroke ("NINCDS") have been generally accepted by the medical profession, and particularly by neurologists, as an authoritative and accurate description of GBS.[3] *See* 3 Annals of Neurology, (June 1978). Under these criteria, clinical, laboratory and electrodiagnostic data are together evaluated in a non-mechanistic manner to determine whether a diagnosis of GBS is appropriate in a specific case. I find the

3. The committee which proposed the NINCDS Criteria was composed of four of the nation's leading neurologists and experts on GBS. The committee consisted of Dr. Arthur Asbury, M.D., Chairman of Neurology at University of Pennsylvania (Committee Chairman), Dr. Herb Karp, M.D., Chairman of Neurology at Emory University, Dr. Dale McFarlin, M.D., Director of Neurologic Research at the National Institute of Health, and Dr. Barry Arnason, M.D., University of Chicago.

NINCDS criteria to be an appropriate standard against which to measure the plaintiffs' proofs and adopt them as controlling herein.

Under the NINCDS criteria, the two features required for diagnosis are:

> A. Progressive motor weakness of more than one limb. The degree ranges from minimal weakness of the legs, with or without mild ataxia, to total paralysis of the muscles of all four extremities and the trunk, bulbar and facial paralysis, and external ophthalmoplegia.
>
> B. Areflexia (loss of tendon jerks). Universal areflexia is the rule, though distal areflexia with definite hyporeflexia of the biceps and knee jerks will suffice if other features are consistent.

I have previously discussed the characteristic monophasic course of progressive motor weakness, plateau, and then gradual improvement that is a diagnostic hallmark of GBS. Areflexia, the second required finding in GBS, is the absence or depression of deep tendon reflexes ("DTRs"). The type of reflex loss finding required to substantiate a diagnosis of GBS is a value less than one-plus or two-plus, which are considered to be in the normal range. This loss of DTRs must occur within days or, at most, a few weeks of the onset of the illness.

It follows as a corollary to this required absence or depression of DTRs that the related pathological reflexes or signs, such as the Babinski and Hoffman, would be similarly absent. The presence of either these pathological reflexes or of increased DTRs (hyperreflexia) would be an indication of central nervous system disease. Other signs of an overwhelming central nervous system involvement, such as a history of mental confusion, dementia, loss of memory and cognitive functions, delirium and agitation, would suggest a diagnosis other than GBS.

The NINCDS criteria next list seven clinical features which are strongly supportive of a diagnosis of GBS. Ranked in order of importance, these are:

1. Progression. Symptoms and signs of motor weakness develop rapidly but cease to progress by four weeks into the illness. Approximately 50% will reach the nadir by two weeks, 80% by three weeks, and more than 90% by four weeks.
2. Relative symmetry. Symmetry is seldom absolute, but usually, if one limb is affected, the opposite is as well.
3. Mild sensory symptoms or signs.
4. Cranial nerve involvement. Facial weakness occurs in approximately 50% and is frequently bilateral. Other cranial nerves may be involved, particularly those innervating the tongue and muscles of deglutition, and sometimes the extraocular motor nerves. On occasion (less than 5%), the neuropathy may begin in the nerves to the extraocular muscles or other cranial nerves.
5. Recovery. It usually begins two to four weeks after progression stops. Recovery may be delayed for months. Most patients recover functionally.
6. Autonomic dysfunction. Tachycardia and other arrhythmias, postural hypotension, hypertension, and vasomotor symptoms, when present, support the diagnosis. These findings may fluctuate. Care must be exercised to exclude other bases for these symptoms, such as pulmonary embolism.
7. Absence of fever at the onset of neuritic symptoms.

The six variants of GBS which have been recognized under the NINCDS criteria are:

1. Fever at onset of neuritic symptoms.
2. Severe sensory loss with pain.

3. Progression beyond four weeks. Occasionally, a patient's disease will continue to progress for many weeks longer than four or the patient will have a minor relapse.

4. Cessation of progression without recovery or with major permanent residual deficit remaining.

5. Sphincter function. Usually the sphincters are not affected, but transient bladder paralysis may occur during the evolution of symptoms.

6. Central nervous system involvement. Ordinarily, Guillain-Barre Syndrome is thought of as a disease of the peripheral nervous system. Evidence of central nervous system involvement is controversial. In occasional patients, such findings as severe ataxia interpretable as cerebellar in origin, dysarthria, extensor plantar responses, and ill-defined sensory levels are demonstrable, and these need not exclude the diagnosis if other features are typical.

The NINCDS criteria further list cerebrospinal fluid and electrodiagnostic features whch are indicative of a diagnosis of GBS:

Cerebrospinal fluid features strongly supportive of the diagnosis

1. CSF protein. After the first week of symptoms, CSF protein is elevated or has been shown to rise on serial lumbar punctures.

2. CSF cells. Count of 10 or fewer mononuclear leukocytes/$mm^3$ in CSF.

Variants

1. No CSF protein rise in the period of one to ten weeks after the onset of symptoms (rare).

2. Counts of 11 to 50 mononuclear leukocytes/$mm^3$ in CSF.

Electrodiagnostic features strongly supportive of the diagnosis

> Approximately 80% will have evidence of nerve conduction slowing or block at some point during the illness. Conduction velocity is usually less than 60% of normal, but the process is patchy and not all nerves are affected. Distal latencies may be increased to as much as three times normal. Use of F-wave responses often gives good indication of slowing over proximal portions of nerve trunks and roots. Up to 20% of patients will have normal conduction studies. Conduction studies may not become abnormal until several weeks into the illness.

Finally, the NINCDS criteria list six features whose presence casts doubt on a diagnosis of GBS:

1. Marked, persistent asymmetry of weakness.
2. Persistent bladder or bowel dysfunction.
3. Bladder or bowel dysfunction at onset.
4. More than 50 mononuclear leukocytes/$mm^3$ in CSF.
5. Presence of polymorphonuclear leukocytes in CSF.
6. Sharp sensory level.[4]

**APPLICATION OF THE "NINCDS" CRITERIA**

Applying the NINCDS criteria to the evidence adduced during the first phase of trial, I find that plaintiffs have produced little or no affirmative evidence to support their contention that the proper diagnosis of Mrs. Stich's condition is GBS. In the paragraphs that follow, I will summarize the evidence applicable to each element of the NINCDS criteria, and will assess whether or not it supports plaintiffs' proposed GBS diagnosis.

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4. The NINCDS criteria also list six features that rule out the diagnosis of GBS; these are, however, inapplicable to Mrs. Stich's condition.

**I. Features Required for Diagnosis**

*A. "Progressive motor weakness of more than one limb."*

At the time of her admission to the Riverview Hospital's Emergency Room on November 27, 1976, four days after the onset of her initial symptoms, Dr. Gluck made several findings relevant to this first criterion. Dr. Gluck's notes of his examination of Mrs. Stich reveal that he found her totally unconscious and convulsing, with muscles of all extremities in spasm, and with clonic convulsions. She had bilateral ankle clonus and normal power in all extremities. A progress note by Dr. Gluck made on November 28, 1976, indicated that Mrs. Stich still had ankle clonus bilaterally and normal power in all extremities.

Further observations were made in the course of a consultation by Dr. Angelo Scotti on November 30, 1976. Dr. Scotti, finding Mrs. Stich more responsive than she had been (in her prior comatose state), recorded that she had good power in all extremities. This observation was confirmed by Dr. Gluck in a progress note of this same date. A further progress note by Dr. Gluck recorded on December 2, 1976, indicated that Mrs. Stich still had moderate muscle spasticity in all extremities but worse on the left, and that her ankle clonus continued. A consultation performed by Drs. Kreider and Gainsburg on December 3, 1976, found, *inter alia* that Mrs. Stich's spasticity in her lower extremities continued. Another progress note by Dr. Gluck on February 10, 1977, indicated that Mrs. Stich's right hand and foot were clenched, and that she had a tremor in her left hand, and that her neck and extremities were rigid. Finally, Dr. Gluck testified that for the period of December 1, 1976, through January 27, 1977, Mrs. Stich's comatose and semi-comatose state precluded any testing

which could conclusively determine her motor strength or the progressivity *vel non* of any motor weakness.[5]

I find that this evidence both fails to affirmatively establish Mrs. Stich's progressive motor weakness and is, in fact, incompatible with the requirements of this first criterion. Dr. Gluck's observations of Mrs. Stich's continuing spasticity[6] and ankle clonus, his findings of normal power in all extremities as late as November 30, 1976, together with the rigidity of her limbs and the clenching of her right hand and foot, are particularly contrary indications. Plaintiffs have offered no credible affirmative evidence which contradicts the "inescapable conclusion" that plaintiffs have failed to establish the presence of this feature.

*B. "Areflexia."*

The second criterion under the NINCDS "Features Required for Diagnosis" is Areflexia, or loss of tendon jerks. The evidence relevant to this is as follows: Mrs. Stich was found to have ankle clonus on November 27th, 28th, 29th, 30th and December 2, 1976. She was found to have Babinski reflexes and/or positive Hoffman signs at various times throughout her initial admission at Riverview Hospital, including November 27th, December 2nd and February 10th. Hyperreflexia, or hyperactive DTRs, were found on November 30th, December 2nd and December 3rd. Each on these observations is inconsistent with, or rules out the presence of, areflexia.[7] Plaintiffs have adduced no affirmative credi-

5. I cannot conclude to a reasonable certainty from plaintiffs' proofs that any of Mrs. Stich's leg weakness is due to progressive peripheral motor weakness. Her inability to walk most likely stemmed instead from disuse atrophy. In support of this conclusion, evidence was adduced by the United States that a comatose patient suffers noticeable disuse atrophy in approximately six weeks.

6. Spasticity is incompatible with GBS, which normally requires a finding of flaccid motor weakness.

7. Dr. Gluck acknowledged that Mrs. Stich's DTRs varied so inexplicably as to be inconsistent with the NINCDS criteria.

ble evidence to contradict the implication of these observations.[8] I must therefore conclude that plaintiffs have failed to meet either of these first two criteria, both of which are characterized by the NINCDS as *required* features for a GBS diagnosis.

While the plaintiffs' failure to meet these two criteria would be perhaps sufficient to rule out a diagnosis of CBS, prudence and the special circumstances of this case[9] dictate that I evaluate each of the other NINCDS criteria to determine whether they suggest a different conclusion.

**II. Features Strongly Supportive of the Diagnosis**

*A. Clinical Features*

The next set of these criteria are those which the NINCDS characterizes as features strongly supportive of a GBS diagnosis. The first of these is progressive motor weakness. The evidence relating to this criterion uniformly fails to establish progression. Mrs. Stich had no symptoms or signs of progressive motor weakness within the ten weeks immediately following her inoculation which are attributable to a cause other than her comatose or semi-comatose state. Her deterioration occurred early and rapidly; during the relevant four-week

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8. I find that the single observation of depressed or absent DTRs (on February 14, 1977, at Columbia Presbyterian Hospital during Mrs. Stich's physical examination following admission) is unconvincing or aberrant, given the measured DTRs on February 16, 21, 22 and 28, 1977. Causes other than peripheral nervous system involvement may explain these inconsistencies in DTRs; muscle atrophy, prolonged bed rest and the relaxation of the patient may all cause an absence of DTRs in a patient.

9. In particular I note first, that the plaintiffs were severely restricted in the proofs that could be presented because of the limited testing which can be performed on a comatose or semicomatose patient such as Mrs. Stich, and second, that GBS was not an early diagnosis by any treating physician and therefore there was little testing performed which was particularly addressed to the NINCDS criteria.

period her condition must be described as chronic. Once again the conclusion which I reach is that plaintiffs have failed to establish that Mrs. Stich's condition is consistent with progressivity.

The second clinical feature strongly supportive of a GBS diagnosis is relative symmetry. The evidence relating to this criterion is limited due to the absence of any evidence of motor weakness in Mrs. Stich's limbs.[10] Nonetheless, there is some evidence which suggests that symmetry is absent in her case. In particular, the obervations by Dr. Pertchik and others that Mrs. Stich had a left gaze preference,[11] that her muscle spasticity was worse on the left than on the right,[12] that she had left-only wrist and ankle clonus, and that at times she had Babinski and Hoffman reflexes only on the left[13] all tend to be incompatible with a finding of symmetry. In the absence of any affirmative evidence, I conclude that this criterion has not been met by plaintiffs.

The next clinical feature strongly supportive of a GBS diagnosis is "mild sensory symptoms or signs". Mrs. Stich's failure to note any sensation of numbness or tingling or other similar sensations at the onset of her symptoms might be considered to be inconsistent with this particular feature. Other than this, Mrs. Stich's comatose or semi-comatose condition prevented any conclusive determination of her sensory symptoms or signs. Thus, I agree with defendant that this feature neither supports nor casts doubt upon a diagnosis of GBS.

The fourth feature under the NINCDS criteria is cranial nerve involvement. Here the only evidence which arguably supports a finding of the presence of this

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10. The import of this evidence is difficult to assess given Mrs. Stich's history of polio, particularly in her left leg.

11. A neurological consultation by Dr. Pertchik on November 22, 1976, found "conjugate gaze preference to left."

12. See report of neurological exam by Dr. Pertchik on December 2, 1976.

13. See progress note by Dr. Gluck dated February 10, 1977.

feature is Dr. Pertchik's observation on November 27, 1976, that Mrs. Stich had a conjugate gaze preference to the left and that her eyes were roving. This observation is by itself inconclusive, however, such a symptom could be the result of either cranial nerve or central nervous system involvement. Otherwise, the evidence fails to demonstrate any possible cranial nerve involvement: There is facial weakness noted, no tongue or muscles of deglutition involvement, she swallowednormally, and her pupils were equal, small, and reactive.[14] I therefore must conclude that plaintiffs have failed to demonstrate by a preponderance of the credible evidence that Mrs. Stich had any cranial nerve involvement.

The next clinical feature cited by NINCDS criteria is recovery. Mrs. Stich has, with therapy, been able to regain only minimal functional abilities, but many of her disabilities are seemingly permanent or chronic, including residual spasticity and general weakness. Further, her recovery, contrary to the usual pattern, did not begin two to four weeks after progression stopped. I find on balance that the evidence is insufficient to find that Mrs. Stich has recovered in accordance with the terms of this feature.

The sixth of these NINCDS features is automatic dysfunction. The signs which would support this feature are entirely absent. No unusual vascular signs were noted, nor were tachycardia or other arrhythmias, postural hypotension, hypertension or vasomotor symptoms. I must therefore conclude that plaintiffs have failed to demonstrate that Mrs. Stich manifested this feature.

The seventh and final clinical feature which under the NINCDS criteria is strongly supportive of a GBS diagnosis is the absence of fever at the onset of neuritic symptoms. Mrs. Stich had a fever from the onset of her earliest symptoms, on November 23, 1976, until at least November 30, 1976. On November 25th she had a fever

14. See report of neurological consultation by Dr. Pertchik on November 27, 1976.

of 102 degrees, on November 27th it was 104 degrees, on November 28th it was 102 degrees, and on November 30th it was 100 degrees. This data is clearly incompatible with the seventh NINCDS feature.

*Variants*

Plaintiffs' proofs more closely fit the six variants on the NINCDS clinical features which are strongly supportive of the diagnosis, but a GBS diagnosis is still not demonstrated by a preponderance of the credible evidence.

The first, fever at onset of neuritic symptoms, is clearly met by the same data which was incompatible with the seventh clinical feature (immediately above). Obviously, a patient who failed to meet one of these features would meet the other, and thus neither finding can be very probative, much less conclusive.

The second variant, severe sensory loss with pain, has not been established by plaintiffs' proofs. Prior to the date she became comatose, Mrs. Stich's senses remained fully intact; thereafter no sensory testing could be undertaken. Thus, this variant feature has not been met.

Progression beyond four weeks is the third variant recognized by the NINCDS criteria. It is difficult to fairly determine whether Mrs. Stich's motor weakness progressed beyond the usual four-week period normally associated with GBS because of her comatose and semi-comatose condition. Further, as I have noted above, there is little evidence to support any progressivity in her motor weakness symptomatology, given the sudden and massive nature of her condition and the overwhelming CNS involvement in the earliest stages. I must therefore find that plaintiffs have not established by a preponderance of the evidence that this variant is applicable to Mrs. Stich's condition.

The next variant is cessation of progression without recovery or with major permanent residual deficit re-

maining. I find that Mrs. Stich's condition fits this variant to some degree, given her residual and chronic functional impairments. I also find, however, that this in and of itself does not confirm a GBS diagnosis. This variant simply allows for a finding of GBS when other features point to such a diagnosis but recovery has not occurred. Such is not the case here.

Variant five is sphincter function. Again, because of Mrs. Stich's comatose state, it is difficult to determine whether her observed occasional urine incontinence is due to bladder dysfunction (which would be consistent with this variant) or merely the result of her inability to express herself. I therefore find that the proofs regarding this feature are inconclusive.

Variant six, also known as the Fisher variant, pertains to central nervous system involvement and was the subject of substantial controversy at trial.

The parties are in agreement that Mrs. Stich's condition involves a substantial CNS component. The extent of that involvement, and more basically whether her CNS manifestations may fairly be linked to a diagnosis of GBS or instead reflect on independent, non-GBS CNS dysfunction, were the subject of much dispute. For the reasons which I will outline more fully below, I find that Mrs. Stich's condition reflects a massive CNS dysfunction and pathology unrelated to GBS, and further that her CNS symptomatology vastly exceeds the type and extent of CNS involvement embraced by Variant Six.

Variant Six expresses the resolution reached by the NINCDS over the proper role of CNS signs or symptoms in the diagnosis of GBS. What Variant Six means is simply that the predominantly peripheral nature of GBS symptomatology need not exclude some CNS signs; in other words, that some evidence of CNS dysfunction in a patient need not exclude a diagnosis of GBS.

The NINCDS criteria lists several examples of CNS findings which may occasionally be found in GBS pa-

tients, specifically ". . . severe ataxia interpretable as cerebellar in origin, dysarthria, extensor plantar responses, and ill-defined sensory levels . . ." Testimony by Dr. Price also indicated that there is some evidence in GBS cases of trace findings of other CNS involvement such as lymphocytes in the cerebrospinal fluid. All pathological evidence of such CNS involvement under Variant Six should be found, if at all, in the cerebellum rather than the cerebrum.[15]

Findings consistent with Variant Six may not, by themselves, form the basis for a proper GBS diagnosis. Only when a patient presents the recognized typical signs of GBS may the accompanying CNS involvement be reconciled with a GBS diagnosis through the variant. As Dr. Shaumberg has testified, "If someone has a very striking picture of peripheral Guillain-Barre Syndrome, the so-called soft central nervous system findings . . . [don't] bother me." A diagnosis of GBS based overwhelmingly upon Variant Six findings would however transform GBS into an entity not recognized by any substantial body of medical opinion and would be akin to "the tail wagging the dog".

This is, however, what plaintiffs here attempt. Mrs. Stich's overwhelming, "disastrous" and "explosive" cerebral involvement bears little or no physiological or pathological resemblance to the relatively mild symptomatology expected under Variant Six. Her tragic comatose and vegetative state, the demonstrable destruction of brain matter, dysfunction of cognition and memory, hemiparesis and disabling spasticity all point to massive cerebral involvement, rather than the expected cerebellar. None of the potential cerebellar findings listed under Variant Six were ever found in Mrs. Stich's case prior to the onset of her coma, and no such signs were (or perhaps could have been) found thereafter.

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15. There is no Computed Axial Tomography (CAT) Scan evidence to suggest any cerebral involvement in GBS cases.

Therefore, I must find that, in addition to failing to demonstrate that the required peripheral nervous system features are present, plaintiffs have also failed to establish by a preponderance of the credible evidence that her CNS involvement properly falls within Variant Six.

*Cerebrospinal Fluid Features Strongly Supportive of the Diagnosis*

The first feature under this next category in the NINCDS criteria calls for an elevation in cerebrospinal fluid ("CSF") protein levels after the first week of symptoms. The evidence establishes that there was an elevation in CSF protein, and I conclude that this criterion has been met.

The second feature in this category involves CSF cells, specifying that counts of ten or fewer mononuclear leukocytes/$mm^3$ in the CSF are consistent with GBS. The evidence pertaining to this feature is contradictory: On November 27, 1976, Mrs. Stich had a cell count of 200; on December 2, 1976, it was 49; and on December 17, 1976, the count was 0, although on that date there was a count of 372 red cells in the CSF. On balance I find that Mrs. Stich's data fails to meet the requirements for this feature.

The NINCDS criteria provide for two variants on these CSF features, the first allowing for no CSF protein rise in the period of one to ten weeks after the onset of symptoms, and the other accepting counts of eleven to fifty mononuclear leukocytes/$mm^3$ in the CSF. Based on the foregoing data, I find that Mrs. Stich's condition may meet the requirements of the second variant (regarding CSF cells).

*Electrodiagnostic Features Strongly Supportive of the Diagnosis*

Under the NINCDS criteria, approximatelty 80% of all GBS cases will have evidence of nerve conduction slowing or blockage at some point in the course of the illness. Conduction velocity is usually less than 60% of

normal, but the process is patchy and not all nerves are affected. The NINCDS criteria suggests that distal latencies may be increased to as much as three times normal.

No evidence of slowed or blocked nerve conduction was presented by plaintiffs. To the contrary, the only evidence presented which related to nerve conductivity (and to this criterion as a whole) was the testing done by Dr. Lovelace on February 16, 1977. This testing showed that at least at that time Mrs. Stich's nerve conductivity (conduction velocities) were normal. I must therefore conclude that plaintiffs have not met their burden to establish by a preponderance of the evidence that Mrs. Stich's condition included this feature.

**III. Features Casting Doubt on the Diagnosis**

The first feature identified under the NINCDS criteria as casting doubt on a GBS diagnosis is a marked, persistent asymmetry of weakness. The issue of whether Mrs. Stich's condition is marked by such an asymmetry is seriously clouded by her history of polio. The record contains several references to her residual polio, some of which suggests that it affects both lower extremities, with the remainder specifying that it affects primarily (or only) the lower left extremity. Discounting the evidence regarding her persistently greater left lower extremity weakness, I still find a marked persistent asymmetry in her condition, with her various symptomatology evincing greater left-side involvement. Several reports by Dr. Gluck and Dr. Pertchik note greater upper limb reflex abnormality on the left than right, a conjugate gaze preference to the left, tremor of the left hand, and other indications of this asymmetry. I therefore conclude that the presence of this feature casts doubt on a GBS diagnosis here.

The next two features which under the NINCDS criteria cast doubt on the diagnosis are (a) persistent bladder or bowel dysfunction, and (b) bladder or bowel

dysfunction at onset. Incontinence of urine was noted for Mrs. Stich following the onset of her coma, but it is impossible to determine whether this was due to dsyfunction or her inability to communicate. For this reason I find the evidence inconclusive as to these two features.

The fourth feature in this category is a finding of more than fifty mononuclear leukocytes/$mm^3$ in the CSF. As I have noted earlier, the first measure of Mrs. Stich's CSF cells, on November 27, 1976, revealed that she then had a count of 200 mononuclear leukocytes/$mm^3$. Although the count was later found to be lower, I find that this initial high level is evidence which casts doubt on a diagnosis of GBS.

The final two features which, under the NINCDS criteria, cast doubt on the diagnosis are (a) the presence of polymorphonuclear leukocytes in the CSF, and (b) a sharp sensory level. The absence of any findings bearing on these features leads me to conclude that they are inapplicable.

In conclusion, I find that plaintiffs have failed to establish by a preponderance of the credible evidence that Mrs. Stich's symptomatology fits the NINCDS GBS criteria. Specifically, I find that plaintiffs have failed to demonstrate that her condition includes the two features required for a diagnosis of GBS, and that they have similarly failed to demonstrate the applicablilty of most of the features which are strongly supportive of such a diagnosis. I find further that plaintiffs' evidence of central nervous system involvement in Mrs. Stich's condition does not meet the standard for Variant Six, and that in any event Variant Six findings in and of themselves are insufficient here to sustain a GBS diagnosis, given the lack of other evidence. Finally, I find that several features are present in her condition which, under the NINCDS criteria, cast a doubt on a GBS diagnosis, even if all other findings had been typical. Therefore, I must conclude that plaintiffs have failed to sustain their burden of proof as to this diagnosis.

**GENERAL OBSERVATIONS REGARDING PLAINTIFFS' PROPOSED DIAGNOSIS**

In the final pretrial order of the multi-district swine flu litigation, the United States stipulated that GBS can be caused by a swine flu inoculation in certain instances. In this case, no doctor who ever either saw Mrs. Stich or reviewed her file prior to this stipulation ever diagnosed her as having GBS. There is no evidence that any doctor even considered that GBS *might* be the correct diagnosis during this period. Prior to November of 1979, neither Dr. Gluck nor any of the consulting neurologists at Riverside Hospital diagnosed her as having GBS or even included it in a differential diagnosis. At Columbia Presbyterian Hospital, where the physicians and neurologists who examined her had the benefit of many of the most advanced and sophisticated nuerological testing procedures, GBS was never even considered to be a plausible diagnosis. Mrs. Stich's medical records simply never established a basis for such a finding.

Mrs. Stich's condition is, as her medical records so clearly demonstrate, overwhelmingly a central nervous system disease. There is no evidence of any peripheral involvement at any time within the first twelve weeks after she received the swine flu inoculation. All symptoms and signs were of indisputable brain damage which devastated the cerebral area. Plaintiffs have failed to meet their burden of establishing that the few arguable peripheral nervous system findings in this record constitute GBS. Nor have plaintiffs demonstrated that her condition is explainable by the GBS variant which recognizes that in certain limited circumstances, where other signs are typical of GBS, findings which may be cerebellar in origin need not exclude the diagnosis. Plaintiffs' suggestion that the definition of GBS be broadened to include the kind of overwhelming CNS involvement as is found in her condition cannot be accepted, particularly where, as here, the essential signs of GBS are absent.

## PLAINTIFFS' EXPERTS

### Dr. Joseph Gluck

Mrs. Stich's primary treating physician was Dr. Joseph Gluck. Dr. Gluck, by his own admission, has ministered to her and been a friend of the family for many years. From November of 1976 until August of 1980, one looks in vain for any mention by Dr. Gluck which even remotely suggests a diagnosis of GBS. The record reflects that in the summer of 1980, Dr. Gluck suffered a heart attack. While recovering, he, as plaintiffs suggest, was "afforded the luxury" of conducting "an exceptionally thorough review of the medical literature concerning Guillian-Barre Syndrome." The doctor, as I observed, brought to court a Niagara of articles, many of which he referred to in the course of his testimony. His thesis, based on his readings, is facially attractive: Since many medical writers, including Dr. Guillian himself (in 1953), have recognized that GBS can have CNS features, he opined that Mrs. Stich's case fits neatly into this diagnostic syllogism.

Defendant has attacked Dr. Gluck's opinion on many grounds: First, that he did not arrive at this opinion until the eve of trial (in September of 1980), thus suggesting, inferentially, that that opinion was colored by a stipulation by the government that it would compensate a causally related GBS. If I felt that Dr. Gluck had persuaded me that his later readings had shed light on this perplexing problem, I would not have been phased by his intensive, albeit tardy, research. However, in listening to Dr. Gluck, and observing him as a witness, I became convinced that I was listening to a physician who had an intense emotional investment in this case. On various occasions he broke down into tears in the course of his testimony. While I am in no way critical of this loss of composure, I do sincerely believe that it reflected a deep personal desire to make up to the Stich family for what he considered to be a serious lapse in

medical judgment during the prior three years. Indeed, there were times when I felt that this expert witness had, by choice, transformed himself into an expert advocate. Considering Mrs. Stich's tragic situation, one can well understand his remorse. However, carefully considered, his opinion must be rejected in the face of the overwhelming amount of contrary clinical and other evidence which has been adduced in this case. Considered together, this evidence suggests that Dr. Gluck's failure to diagnose Mrs. Stich's condition as GBS from November 1976 to September of 1980 was not incompetence.

**Dr. Howard Medinets**

Dr. Howard Medinets' opinion as to diagnosis and causation on behalf of the plaintiffs is rejected by this court for somewhat different reasons. Dr. Medinets has been practicing neurology and neurosurgery since 1950. He felt that Mrs. Stich suffered from encephalomyeloradiculopathy. He testified that she had both peripheral nervous system and CNS involvement. Boiled down, it was Dr. Medinets' conclusion that Mrs. Stich's peripheral neuropathy could be classified as a GBS and her CNS pathology as a meningo-encephalitis. While I have considerable regard for Dr. Medinets' qualifications, I find that his opinion as to diagnosis and causation is unpersuasive. For example, Dr. Medinets ruled out Herpes Simplex Encephalitis because of the results of the complement fixation test, the validity and efficacy of which was seriously questioned by the recent research referred to in the testimony of Drs. Price and Whitely (discussed *infra*). I am convinced that Dr. Medinets was not sufficiently discriminating or meticulous in giving consideration to the various possible causes of Mrs. Stich's condition, particularly those relating to a viral etiology.

**Dr. Charles Poser**

Dr. Charles Poser had no hesitation in causally relating Mrs. Stich's condition to the swine flu inoculation she received or in diagnosing it as GBS. His precise diagnosis was that she had an encephaloradiculoneuropathy. He felt that her condition falls within the spectrum of diseases described in the medical literature as disseminated vasculomyelinopathy, and which could be diagnosed neurologically as GBS. He also had no hesitation in stating that Mrs. Stich's neurological conditions met the requirements of the NINCDS criteria.

It was obvious to me that while the doctor has had extensive interest in and exposure to GBS, his opinion as to the nature of that condition is a distinctly minority view, and not one shared by an overwhelmingly impressive body of medical opinion. In listening to Dr. Poser, I had the distinct impression that his was a "voice crying out in the wilderness". If I felt that his theory, as applied to the facts of this case, made sense in light of the evidence presented, I would have no hesitation in embracing his rationale. I decline to do so, however, because I find that his general opinion as to the nature of GBS is contradicted by the overwhelming weight of credible medical opinion presented to this court. Secondly, his diagnosis in this particular case is, in my judgment, faulty. I had the distinct impression that Dr. Poser took the pathological picture presented by Mrs. Stich in this case and attempted to mold it to fit his own almost unique theories. A square peg cannot fit into a round hole. Although I was highly interested in this theories, I find that they do not form a sufficient qualitative basis in this case to permit me to conclude that plaintiffs have met their burden of proof.

**Dr. Robert Lisak**

The record will reflect that I questioned Dr. Robert Lisak extensively. His expertise in the field of neurology

was conceded by the government. After acknowledging his familiarity with the NINCDS criteria, he acknowledged that his "boss", Dr. Arthur Asbury, (chairman of the NINCDS Committee) had "made them [the criteria] up". It was his opinion that Mrs. Stich had post-immunization encephalomyelitis, and that she also had "involvement of the nerve roots or possibly of the peripheral nerves as well, which would then give her encephalomyeloradiculitis. The radiculitis would be compatible or a part of the Guillain-Barre Syndrome." With respect to her central nervous system condition, it was his opinion that she was suffering from acute disseminated encephalomyelitis (ADEM).

I think it is fair to conclude that, after extensive questioning on my part, the doctor stated that he felt that Mrs. Stich's condition fit the NINCDS criteria, particularly Variant Six. In this process I had attempted to carefully ascertain that I understood where Dr. Lisak stood with respect to this extremely difficult case. After questioning Dr. Lisak, I felt that the opinion he expressed regarding the diagnosis was couched with considerable hesitancy. He appeared to be far more certain regarding the problem of causal relationship between the inoculation and alleged result than he was with diagnosis. I was quite impressed with the quality of his testimony, yet I retain serious doubts whether his hesitant and perhaps vacillating opinion provides a sufficient basis for plaintiffs to carry the day.

## GENERAL CONCLUSIONS REGARDING EXPERT TESTIMONY

I was also tremendously impressed by most of the testimony presented by video deposition, which significantly undermined the general theses offered by Drs. Poser and Gluck. While I acknowledge Dr. Neil Nathanson's eminence in the field of epidemiology, it is my opinion that an epidemiological solution to this particular problem is not one which I can adopt, either way.

In sum, I find that, when carefully evaluated, plaintiffs' essential thesis strains my credulity. The net impression I have is that plaintiffs' expert witnesses made a valiant effort to persuade this court on the issues reserved for this phase of the case. That effort, I find, has failed, for reasons I have expressed and will express later in the body of the opinion.

**THERE IS NO EVIDENCE OF A DEMYELINATING PERIPHERAL NEUROPATHY**

As defined earlier, GBS is clearly a demyelinating peripheral neuropathy. As Dr. Medinets testified, demyelination involves the stripping away of the myelin sheath around the nerve, the result being that a demyelinated fiber cannot conduct any nerve impulses at all. Despite the interpretation of the EMG reports in this case by plaintiffs, I find that there is insufficient credible evidence of peripheral nerve involvement in Mrs. Stich's upper extremities at any time. Dr. Medinets noted that slowed nerve conduction, or absence of conduction, does not necessarily mean demyelinating disease.

And further, the EMG reports of Drs. Lovelace and Anayotis (and the interpretation of these reports by Drs. Tsairis, Price and Goodgold), which I will more fully discuss below, indicate that there is no persuasive evidence of a demyelinating peripheral neuropathy. On the contrary, Mrs. Stich's condition manifested itself overwhelmingly in the central nervous system.

Dr. Lovelace, in his report dated February 16, 1977, concluded that Mrs. Stich showed evidence of lower motor neuron disease at the anterior horn cell level. That conclusion, as evidenced by the normal conduction velocities on EMG, indicates that plaintiff was suffering a CNS disorder, not a demyelinating peripheral neuropathy. Two factors make this conclusion inescapable. First, there was no evidence of slowed conduction, as motor conduction was found to be normal. Second, the

involvement of the nerve was at the anterior horn cell level which is part of the central nervous system, not the peripheral nerves. Thus, because of the lack of findings supportive of a demyelinating peripheral neuropathy, Dr. Lovelace's EMG report is not evidence that Mrs. Stich had GBS; in fact, it supports the contrary conclusion.

A similar conclusion must be drawn from the report by Dr. Anayotis from March 1980. The most that can be fairly drawn from this report is that some denervation can be identified. There is no basis, however, for finding demyelination of the peripheral nerves. Further, Dr. Price testified that Dr. Anayotis was wrong to base his conclusion on a single conduction velocity (right perineal nerve) that is low normal, not abnormal. Dr. Tsairis found that the denervation that was identified on EMG testing involved both lower extremities was consistent with denervation of some part of the lower motor neuron but not consistent with damage to the motor axon (*i.e.*, not peripheral).

The Anayotis report also identified fibrillations in several muscle groups. This is not significant, however, because one does not find fibrillations or fasciculations in a demyelinated peripheral nerve; fibrillations, as Dr. Medinets testified, are, rather, a definite indicator of anterior horn cell involvement. In fact, because of the involvement at the anterior horn cell level, any absence of conduction on the peripheral nerve is more likely secondary to a central nervous system condition. In summary, Dr. Anayotis' EMG study, including the F wave response and the conduction velocities, is not compatible with a peripheral neuropathy.

Both Dr. Lovelace's and Dr. Anayotis' reports were subject to the scrutiny and analysis of Dr. Joseph Goodgold in Dr. Goodgold's deposition testimony on October 27, 1980. Dr. Goodgold, director of the Electrodiagnostic and Neuromuscular Service at New York Hospital and a prominent expert in his field, found that

these two reports, even considered together, could not support a diagnosis of GBS. Several factors contributed to this judgment. First, much emphasis was placed by plaintiffs upon the motor conduction velocity of the right perineal nerve from the head of the fibula to the ankle which Anayotis reported as 45 meters/sec or *low normal.* That measurement, however, is considered and recorded as *normal* in Dr. Goodgold's laboratory (as well as in Dr. Tsairis' laboratory).

Further, in referring to the fibrillations identified by Anayotis, Dr. Goodgold testified that he cannot tell one way or the other whether they are evidence of GBS or anterior horn cell disease. In fact, Dr. Goodgold admits that he cannot rule out anterior horn cell disease as the cause because he does not have enough information from Anayotis' report or from Lovelace's report to rule it out. In referring to the inability to obtain conduction velocities in the lower extremities, Dr. Goodgold agreed with Dr. Tsairis that the reason they could not be obtained was "because of the severe atrophy due to extensive denervation in all distal muscles on the needle EMG study", [and not because of peripheral demyelination].

Dr. Goodgold also found that the fibrillation potentials which Dr. Lovelace found (which plaintiffs suggest is a subclinical sign of peripheral nerve involvement) are not reliable because of atrophy and residual weakness due to Mrs. Stich's history of polio. As Drs. Price and Tsairis confirmed, it is known among polio specialists and electromyographers that old polio will produce EMG abnormalities for many years — greater than twenty and perhaps up to sixty — after the acute phase of the polio has passed. Mrs. Stich's left leg was clearly involved with polio and muscle loss was the residual deficit. Whether the right leg was also clinically involved is unclear from the medical records, but it is quite likely that the right leg was at least sub-clinically involved with polio. Dr. Tsairis, whose subspecialty is electromyography, testified that he knew of many cases of old polio

in which the patient believes only the left leg to be affected, but sensitive EMG studies will show right leg denervation as well. Recent research confirming this phenomenon was also brought to the Court's attention by him.

Here, I agree with defendant that Mrs. Stich's left leg EMG findings by Dr. Anayotis of fasciculations in March of 1980 were identical to those in the right leg; that the left leg has findings characteristic of old polio supports the proposition that the right leg was also previously involved, leaving a similar deficit at the anterior horn cell level. Polio is, of course, an anterior horn cell disease. The Lovelace EMG finding of a disease process at the anterior horn cell level is consistent with the findings one would expect in the EMG of a muscle affected many years before with clinical or subclinical old polio. Accordingly, the electromyographic findings which have been interpreted as indicative of anterior horn cell disease may indeed by arising from the polio involvement that plaintiffs' experts chose to ignore.

Finally, the Lovelace report is the only arguable evidence of denervation of the facial nerves in this case. It is highly significant that neither Dr. Lovelace nor Dr. Goodgold concluded that this was proof of peripheral nerve demyelination. Lovelace instead identified the involvement at the anterior horn cell level, which, as I pointed out previously, is in the central nervous system. The face fibrillations in the Lovelace report, which are rated at one-plus, are, as Dr. Price testified, minor subclinical nonspecific findings. GBS can never be diagnosed from an isolated finding of fibrillations, which are not tantamount to weakness.

For all of the above reasons, the EMG evidence fails to prove that Mrs. Stich suffered from a demyelinating condition of the peripheral nerve in 1976 or at any subsequent time. Dr. Goodgold's opinion, that he cannot conclude from these reports that there is evidence of demyelinating peripheral nerve disease to a reasonable

medical probability, casts substantial doubt on the plaintiffs' position.

**MRS. STICH'S CONDITION IS A VIRAL ENCEPHALITIS: MOST PROBABLY HERPES SIMPLEX ENCEPHALITIS**

The record indicates that virtually every treating physician's diagnosis was either encephalitis, encephalomyelitis, or encephalitis of unknown etiology. The final discharge diagnosis at Columbia Presbyterian Hospital was also viral encephalitis. After carefully reviewing the evidence, I find that Mrs. Stich's condition is, to a reasonable medical and legal certainty, Herpes Simplex Encephalitis.

Encephalitis is an inflammation of the brain. Viral encephalitis is the most common form of encephalitis and is usually characterized by localized lesions in the brain. HSE, in turn, is the most frequently found viral encephalitis in humans, and is caused by the herpes simplex virus. This virus is usually benign, but for unknown reasons it may attack the temporal lobe or the inferior part of the frontal lobe, thereafter sometimes extending back into the occipital, parietal and frontal areas.

In HSE cases the virus typically causes localized involvement first, with affected brain cells becoming swollen and edematous. The disease, as detected by such edema, normally begins in the gray matter, but may spread through the white matter (neural tissue which typically underlies the cortical gray matter, or is gathered into central tracts and peripheral nerves) as the infection progresses. The acute phase of HSE, with the virus infecting the cortex and subcortical white matter, leads eventually to severe necrosis. The host eventually may bring the virus under control, but not before irreversible brain damage is done. Where HSE is untreated, the infection may become bilateral, meaning that the op-

posite side of the brain may become involved, and the virus may continue its destructive process.[16]

HSE, as a predominantly focal disease, usually produces neurological signs on the opposite side of the body from the sector of the brain which is involved; such signs include central nervous system weakness, focal seizures, one-sided pathological responses, and hemiparesis (implying frontal area involvement) or hemianopsia (implying occipital area involvement). Onset of HSE is typically accompanied by fever and headache, focal neurological symptoms, behavioral disturbances, and altered consciousness. HSE is the most common non-epidemic cause of fatal rapid-onset disorder of the central nervous system; it is a devastating condition which is fatal for approximately 75% of all patients. Those who survive suffer a severe neurologic deficit due to destruction of part of the brain. The typical residual disabilities include hemiparesis and disorders of cognition, thought and memory.

*Diagnosis of HSE*

The credible testimony indicates that the only sure method to diagnose HSE is by a brain biopsy of the affected brain material.[17] Mrs. Stich, of course, never had a brain biopsy performed, primarily because her transfer to Columbia Presbyterian Hospital occurred too late in the course of her condition to provide the opportunity for a meaningful test. Reliance must therefore be placed instead on the recent advances in the diagnostic tools available for establishing an HSE diagnosis to a medical and legal certainty.

Primary among the recent diagnostic advances is the work of the National Institute of Allergy and Infec-

16. Upon biopsy or autopsy of the brain in an HSE case, the presence of the virus will be found bilaterally but in larger quantities where the disease began.

17. Even a negative brain biopsy may not be wholly reliable in ruling out an HSE diagnosis because of the possibility that the affected site will be missed by the biopsy procedure.

tious Diseases ("NIAID") Collaborative Antiviral Study Group, and particularly that of its principal investigator and director, Dr. Richard Whitley, The protocol of the Collaborative Antiviral Study Group is the diagnosis and therapy of HSE. The group began with the participation of thirteen medical institutions, and this number expanded to twenty-two in 1976. By 1981, there were forty-five participating medical institutions throughout the United States, Canada, England and Sweden. The Group has had the benefit of the study of two hundred and fifteen patients presenting signs of encephalitis, each of whom has undergone a biopsy. The results of these studies, first reported in the medical literature in August of 1977[18] and in various scholarly articles thereafter, have provided the medical community with the best available means, other than (or prior to) biopsy, of predicting whether a given patient has HSE. In practice, the Group's findings are regularly employed as the criteria for establishing a tentative HSE diagnosis, which would, in turn, lead to a biopsy procedure to confirm the diagnosis and, if confirmed, admit the patient to an experimental antiviral drug therapy. I adopt the NIAID Collaborative Antiviral Study Group's findings or criteria for the limited purpose of determining whether or not the evidence herein suggests that HSE is the most probable diagnosis of Mrs. Stich's condition.[19]

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18. This seminal report of the Group was published as Whitley, et al., *Adenine Arabinoside Therapy of Biopsy-Proven Herpes Simplex Encephalitis*, and appeared in the new England Journal of Medicine, Volume 297 at pages 289-294 (August 1977) (Exhibit D-37).

19. Although doctors at Riverview Hospital treating the plaintiff in late 1976 and early 1977, during the acute phase of her illness, did not have the benefit of the Collaborative Study publications, they nonetheless considered HSE. The diagnosis of HSE was likewise considered by the physicians at Columbia Presbyterian and later in the discharge from Riverview to Morris Hall. In fact, Dr. Poser testified that HSE is the most common viral encephalitis, and it is the only one that should be considered seriously in New Jersey in the winter.

It has been known for some time that HSE, being primarily a focal encephalitis, may be detected through the use of Computer Axial Tomography ("CAT") and technetium radionucleid-type brain scans and electroencephalographs ("EEGs") which may reveal the location of focal lesions in the brain. The presence of such focal lesions would support the diagnosis of HSE and contraindicate the diagnosis of post-vaccinal encephalitis. The Collaborative Study Group has found that the EEG, brain scan and CAT scan are the three best non-invasion (non-biopsy) tools or studies to correctly predict an HSE diagnosis. Clinical findings alone, such as fever, CSF pleocytosis, consciousness and convulsions, have been found insufficient in and of themselves to predict or confirm such a diagnosis, although they may create the initial suspicion.

The Collaborative Study Group has recently published its most current research in an article in the Journal of the American Medical Association. *See* Whitley, *et al., Herpes Simplex Encephalitis: Clinical Assessment, Journal of the American Medical Association*, January (1982). The essential data included in that article summarizes the Group's experience with 176 patients who presented with signs of focal encephalitis. All of these patients were biopsied at the suspected brain site; as a result, a diagnosis of HSE was confirmed in 101 patients and not confirmed in the remaining 75. The data which the Collaborative Group collected were then analyzed to determine whether there were findings and symptoms which were common to the HSE group as distinguished from the non-HSE group. All tabulations were verified by virologists, neurologists, and biostatisticians, who checked by double-blind methods for the accuracy and proper categorization of the patient data. The resulting findings are reproduced here as Table 1:[20]

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20. The data was included in the article as Table 4.

**Table 1**
**Herpes Simplex Encephalitis**
**Diagnostic Assessment**
**Within Three Days of Biopsy**

| EEG | Brain Positive | | Brain Negative | |
|---|---|---|---|---|
| Focal | 58/73 | (81%) | 39/66 | (59%)* |
| Generalized | 44/72 | (61%) | 41/62 | (68%) |
| Spikes | 40/70 | (57%) | 14/58 | (24%)* |
| Slow Activity | 65/72 | (90%) | 52/62 | (83%)*** |
| Brain Scan Localization | 37/74 | (50%) | 6/44 | (14%)* |
| CAT Scan Localization | 33/56 | (59%) | 8/37 | (22%)** |
| Any one or More Assessment of Localization | 83/101 | (82%) | 47/75 | (60%)* |
| Two or More Positive Results | 31/64 | (48%) | 9/50 | (18%)* |

*P = 0.001
**P = 0.01
***P = NS

Defendant's point out and I agree that there is a statistically significant difference between the incidence of focalized EEG, brain scan and CAT scan in the brain positive (*i.e.* actual HSE) group of patients. A focal EEG was found in 81% of the HSE group (59 out of 73 patients), and only 59% of the brain negative (*i.e.* non-HSE) group of patients. Similarly, spiked wave activity was found in the EEG of 57% of all HSE cases, but only 24% of the non-HSE cases.

Generalized EEG activity was, however, a common feature of both groups, being found in 61% of the HSE patients and 66% of the non-HSE patients. Slow activity was also a common EEG feature of all patients who presented with signs of focal encephalitis, being present in 90% of the HSE group and 84% of the non-HSE group.

While it would be incorrect to conclude from this data that HSE has a pathognomonic or uniquely characteristic EEG, the presence of such focalized activity and sharp wave spikes does make HSE a more likely diagnosis for a given patient than any other type of encephalitic condition.[21]

The Collaborative Study Group also found that CAT scans are a useful diagnostic tool in HSE cases. While there are numerous reports of HSE CAT scans in the literature, their research confirmed that in CAT scans of a patient in the acute phase of illness one expects to find localization of involvement in the attack area and those areas to which the disease has spread. The Collaborative Study Group found CAT scan localization in 59% of the HSE cases (33 of 56 patients), but in only 22% of the non-HSE cases (8 out of 37 cases). The Collaborative Study Group found this difference to be statistically significant at the 99% level of confidence.

Similarly, the Collaborative Study Group found that the technetium radionucleid-type brain scan is a useful method for showing disruption of the blood brain barrier in Herpes Simplex Encephalitis cases. The brain scan provides a good early warning of the areas which may be involved, although it does not necessarily give the precise location of the HSE lesions. The Collaborative Study Group found that 50% of the HSE patients had evidence of brain scan localization (37 out of 74 patients); only 14% of the non-HSE cases (6 patients out of 44) exhibited localization on their brain scan. Thus, a patient with a focal brain scan is more likely to have HSE than any other encephalitis. The statistical level of confidence for this difference was found to be 99.9%.

Overall, one finds at least one instance of localization (either EEG or brain scan or CAT scan) in 82% of

21. These focal changes, particularly the sharp waves and spikes, which are often accompanied by generalized background abnormality in the EEG, are thought to be caused by the irritative area of infection of the Herpes disease process.

the HSE cases (83 out of 101 patients), but in only 60% of the non-HSE cases (47 out of 75 patients). The evidence is even more compelling with respect to a finding of two or more positive results. One finds that when the EEG, brain scan, and CAT scan are performed, two or more of those indicators will show localization in 48% of the HSE cases, but in only 18% of the non-HSE cases. The statistical measure of confidence for these differences was found to be 99.9%.[22]

Finally, the Collaborative Study Group and others have documented the typical HSE or viral encephalitis findings with respect to an analysis of cerebral spinal fluid. Ordinarily, the patient will show an elevated opening pressure, an elevated white blood cell count (usually mononuclear lymphocyte rather than polys), elevated protein, normal glucose, and red cells may be present.

In sum, the research of the Collaborative Study Group has led me to the conclusion that HSE may be presumed if a patient presents with altered mentation, fluctuating consciousness, signs of central nervous system disorder, localization through neurological or clinical findings, localization established through the diagnostic tools of the CAT scan, EEG or brain scan, and CSF findings compatible with the presence of a viral infection.

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22. Special attention was paid by the Group to finding an explanation for why nine (9) patients who were not found to have HSE nonetheless had positive focal findings in at least two of the three indicators. (See Exhibit D-46.) Alternative explanations were clearly identified in all nine (9) cases. The diseases, which produce results (by CAT scan, EEG and brain scan) mimicking HSE in these patients, were found to be as follows:

Three brain abscess cases
One cryptococcal disease case
Two Epstein-Barr virus cases
One toxoplasma gondii infection case
One tuberculosis case
One brain tumor case.

When the facts of this case are applied to the findings of the Collaborative Study Group, the conclusion is inescapable that Mrs. Stich's condition is Herpes Simplex Encephalitis, and that she is today left with the residuals of that disease. The evidence clearly establishes that it is approximately 85% probable that the plaintiff had HSE, because of the strong focalization factors and other evidence.

When Mrs. Stich was first admitted to the Riverview Hospital Emergency Room she had clear signs of focal encephalitis which were quickly confirmed by evidence of localization on her EEG, CAT scan and brain scan.

The EEG evidence from the acute phase of her illness showed focal sharp waves and spikes typical of HSE. Such abrupt wave signs are indications of discharges from the cortex associated with focal seizures. The spiked wave activity and slow wave component in the EEG results for Mrs. Stich showed focal impairment localized on the posterior aspect of the right temporal lobe. It was also noted that the background frequency on Mrs. Stich's EEGs slowed, showing an overall picture indicative of HSE.[23]

Mrs. Stich's CAT scans provide further evidence of focal involvement. Dr. Price testified that CAT scans in confirmed HSE cases have been seen that looked remarkably similar to those found in this case.

In HSE cases, the earlier CAT scans are the more important because they show more extensive and focalized disease and greater edema throughout the brain; later in the disease process, edema is lessened and brain substance is lost, thereby causing CAT scan results to be less indicative or reliable.

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23. I find that the testimony by Dr. Poser that sharp waves and spikes were not present on the EEG (Transcript at 1277) is incorrect, and his basis for ruling out the diagnosis of HSE on this ground is erroneous.

Mrs. Stich's first CAT scans, taken on December 4, 1976, are distinctly abnormal. The inferior portion of the frontal lobe and the temporal lobe are abnormal, and edema is present throughout the medial frontal region and the temporal region; there are severe temporal and inferior temporal abnormalities on these scans, with an obvious mass effect pushing from right to left and shifting the midline of the brain. The generalized edema in the temporal lobe extends through the temporal/occipital region in the lower parts of the brain. Her earliest CAT scan shows involvement on the left side which is bad but on the right side which is much worse. Such involvement through these two focal areas of involvement, one in each temporal area, is consistent with HSE.

The lower CAT scan cuts are important because they show the temporal lobes which bear the brunt of HSE involvement. If this were instead a white matter disease, the involvement would show in the middle two higher cuts. In fact, there is less abnormality as one goes up into the white matter. The pathology shades from very abnormal down low into close to abnormal up higher, with the focal pathology being present in the temporal areas.

By December 27, 1976, the CAT scans taken of Mrs. Stich showed evidence of reduced edema. Abnormalities were noted in the medial inferior frontal region in the lower cuts, while the higher cuts do not appear to be abnormal. Gray matter atrophy appears to have caused the enlargement of the Sylvian Fissure noted in later CAT scans. Other findings are present which are not well delineated, suggesting, as Dr. Price noted, that the disease has spread. The December 27, 1976 CAT scan is not inconsistent with HSE.

The February 17, 1977 CAT scan series reveals a doughnut lesion in the cortex near the posterior temporal/occipital junction, close to the surface. This most likely represents an area of necrosis with surround-

ing reaction, rather than an area of active hemorrhage. The white matter in the upper cuts appears to be normal, suggesting (as did the earlier CAT scans) that this disease process is not ADEM, because ADEM is not a cortical (gray matter) disease.

The March 7, 1977 CAT scan is similar to the February 17th series. It is unclear from the two series whether the doughnut-shaped ring is the same or slightly decreasing in size. Both are consistent with a diagnosis of HSE, showing the breakdown of tissue and a decrease in edema. As Dr. Price testified, a CAT scan, if taken today, would be likely to show the loss of brain substance and atrophy which is the residual legacy of the HSE pathological process.

The technetium brain scans performed on Mrs. Stich on December 2 and December 9, 1976, were also abnormal and focalized. Although the December 2nd brain scan had become unavailable as of the time of trial and was therefore not introduced into evidence, a report written by Dr. Pertchik (based on this brain scan) described a lesion in the right side of the brain, which is suggestive of a finding in line with the NIAID Collaborative Study Group's criteria.

Even without the perhaps uncertain brain scan evidence, however, Mrs. Stich had two of three findings for localization on the right side of the brain during the critical first seven days of her hospitalization. Patients having at least two positive results on these parameters, according to the findings of the Collaborative Study Group, will have a significantly higher probability of having HSE than another disease. The data show a significant difference between HSE and non-HSE cases on this point at a 99.9% confidence level.[24] From the findings of

24. When one considers that the technetium brain scan of December 2 also suggests a finding of focality of the brain lesion area, all three neurodiagnostic tools — EEG, CAT scan, and brain scan — are positive for focality during the first seven days of hospitalization, as the patient was lapsing into unconsciousness and coma.

the biopsy studies of 176 patients of the Collaborative Antiviral Study Group, these findings must be interpreted as HSE in 31 out of 40 cases of patients presenting with two or more positive results, with the remaining nine cases having been explained as viral-related conditions, brain abscesses, and tumor. Out of 176 patients studied, none fitting the plaintiff's profile had a disease other than HSE or one of this group of circumscribed viral encephalitis or brain abscess or tumors.

The cerebrospinal fluid (CSF) findings from Mrs. Stich lend further support to a diagnosis of viral encephalitis, and particularly of HSE. The white cell counts in Mrs. Stich's samples are highly significant. HSE patients have a higher white cell count than non-HSE patients in their cerebral spinal fluid. The presence of elevated counts of white cells, and particularly of lymphocytes, is a sign that the body is fighting an infection of the brain.[25] In this case, Mrs. Stich's CSF white cell count of around 200 cells is typical of the HSE case. The lymphocytes in particular predominate in her CSF findings. The cells go from 92% lymphocytes on November 27 to 97% lymphocytes on December 2. Again, during the acute phase of illness, the CSF findings concerning white blood cells are highly confirmatory of HSE.

The elevated opening pressure in the spinal taps, where readings were taken, should also be noted. An elevated CSF pressure is characteristic of HSE, as it is caused by the increased intracranial pressure resulting from the swelling of the brain cells. The opening pressure of 350 in the December 2, 1976, spinal tap is distinctly abnormal and is a characteristic finding in the acute phase of an HSE case: The opening pressure trend decreases, diminishing as the acute phase of HSE

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25. Another type of white cells in the CSF are polymorphonuclear leukocytes, which are also a sign of the body fighting acute infection, especially bacterial infections. Because HSE is a viral infection, these cells are not normally found in such cases.

passes, and it was reduced in this case to 190 on February 12 and 110 on February 15, 1977.

The findings of red cells in the CSF is a fairly consistent finding in HSE cases: Blood may be spilled into the spinal fluid because HSE is a hemorrhagic disease in which the blood/brain barrier is injured. The finding of red cells (at levels of between ten and five hundred or more cells) is not specific as to HSE but is a relatively common finding in HSE cases. Mrs. Stich's red blood cell count findings went from eight to twenty-four to three hundred seventy-two to one to thirty-one. These findings are consistent with a diagnosis of HSE. Although some experts have said that elevated red cells in the CSF are "unequivocal evidence" of HSE, the findings of the Collaborative Study Group do not compel such a conclusion, as the pattern of red cell findings in HSE patients is not uniform.

In this case xanthrochromia — a yellow tinge to the cerebral spinal fluid — was also detected. Xanthrochromia is a characteristic finding in HSE cases because it is evidence of the presence of red cells in the CSF which have released hemoglobin. This hemoglobin is then converted to bilirubin, giving the fluid a characteristic yellow tinge. Xanthrochromia was specifically noted in the December 2 spinal tap, suggesting earlier hemorrhage

Finding of elevated CSF protein is another nonspecific finding which supports the diagnosis of HSE. The elevation of protein is caused by the destruction of brain tissue and its breakdown within the CSF, which is also consistent with viral encephalomyelitis. Moreover, the persistent rise in CSF protein in this case may be caused by the diabetic condition superimposed upon the HSE.

It should be further noted that the presence of white cells in this case, particularly lymphocytes, when accompanied by increased CSF protein, is a condition of pleocytosis which is a characteristic of HSE and practically unknown in GBS cases.

The attack site in the brain and involvement of the various brain lobes in Mrs. Stich's condition provides additional support for an HSE diagnosis. Generally, the temporal lobe is the most common attack site for the Herpes virus, in 80-85% of the cases. The frontal lobe is attacked in 7-8% of the cases, as is the parietal lobe. The occipital lobe is the principal attack site in only 1-2% of HSE cases. The greater incidence of HSE involvement in the temporal lobe is caused by its greater susceptibility to the virus. In the present case, temporal lobe involvement was seen in the earliest CAT scans, as noted above, and the EEG detected abnormality in the rear temporal/parietal/occipital junction. Support exists in the medical literature for such a combination of focal abnormalities in HSE patients. In a study of 11 patients with confirmed HSE, 5 had abnormal CAT scans of which 3 showed extension into the occipital region of the brain. Dutt, *et al.*, *Computed Tomography and EEG in Herpes Simplex Encephalitis*, 39 Archives of Neurology (1982). (Exhibit D-53). Focal abnormalities in the EEG were also seen in two of the three patients exhibiting occipital area involvement. *Id.*

The findings of right brain involvement by CAT scan, EEG and brain scan were confirmed by the neurological symptoms manifested on the opposite side of the body, namely: eyes were deviated to the left, the left arm was spastic, edema shifted the brain from right to left, a left Babinski reflex was noted, left central nervous system facial weakness was noted. It is clear that the right brain had more involvement than the left from the start, a status which is reflected in the symptoms that continue today.

Finally, the course of Mrs. Stich's condition, from onset until today, is typical for HSE. The onset of the plaintiff's disease was typical, manifested by high fever, abnormal behavior, focal seizures, eyes deviated to the left, elevated protein, white cells, in CSF, and rapid progress toward coma.

After onset, the course remained typical of HSE, presenting severe motor difficulties of the upper motor neuron type (*i.e.*, originating in the central nervous system). These upper motor neuron motor difficulties included the left hemiparesis noted at Columbia, the left upper motor neuron facial paralysis, the left arm and left leg spasticity, the severe disorder of all four extremities, predominantly the left side. This course was indicative of supra-temporal destruction of brain with residuals caused by HSE. The signs of central nervous system involvement included exaggerated reflexes, the Babinski reflex, spasticity, ankle clonus, and abnormal EEG. (Gluck at 2674.)

Mrs. Stich's mental status deteriorated as coma eventually resolved into a persistent vegetative state. Today, marked memory disorder and numerous problems in the cognitive spheres continue to persist, all of which are hallmarks of HSE. The present condition shows obvious sequelae of severe encephalitis, including serious dysfunction of cognition, memory, behavioral changes, and impaired higher cortical functions; there continues to be marked upper motor neuron type (*i.e.*, central nervous system) difficulty in all four extremities, predominantly the left, and especially in the legs. The continued spasticity today is another example of a typical residual of Herpes Simplex Encephalitis, and it is noted that medications for spasticity have continued since the early course of this disease.

The left homonymous hemianopsia, a central nervous system disorder, has continued to the present time. The left hand and arm disorders are upper motor neuron type, as is the continued inability of cerebral functioning such as inability to recognize objects and words. Prospects for recovery from this type of disease were very bleak by the time Mrs. Stich was transferred to Columbia Presbyterian. Mrs. Stich's condition is typical of the survivors of HSE; 28% of the HSE victims survive, of whom half manifest severe sequelae for life.

Mrs. Stich's age and gender tend to provide additional support for the HSE diagnosis. According to the research of the Collaborative Antiviral Study Group, the fact of being female makes it a little more likely that this encephalitis is HSE. An even stronger corelation to HSE exists from the fact that Mrs. Stich is over fifty years old; of people presenting with signs of focal encephalitis, among those over fifty years old, twice as many have HSE as non-HSE. Thus, Mrs. Stich, who was fifty-one years old at the time of onset, is twice as likely to be correctly diagnosed as having HSE than another form of encephalitis.

The absence of serological titer rise does not substantially affect the diagnosis of HSE. Several of the plaintiffs' medical experts attempted to cast doubt upon, or completely rule out, a diagnosis of HSE based upon the fact that the assays of Mrs. Stich's serum did not show the expected four-fold titer rise over time. Applying conventional wisdom, this absence of a four-fold titer rise was considered incompatible with HSE by Drs. Poser and Medinets. Of the plaintiffs' experts, only Dr. Lisak admitted that a lack of titer rise does not rule out HSE, although he, too, thought that the lack of a titer rise meant that it is not likely that this disease is HSE. Dr. Lisak noted, however, that he was unaware of the Collaborative Antiviral Study Group findings on this subject.

The Collaborative Study Group's recent research has, in fact, disclosed that the titers in confirmed HSE victims does not show a four-fold rise over time in fully one-half of such patients, when the testing for such a four-fold rise is conducted by the same methods as utilized in this case. The four methods of antibody assessments for HSE are: complement fixation, pressive hemagglutination, neutralizing antibodies, and immunofluorescence IgG antibodies. Here the antibody assessment was done by the complement fixation

method, which has been found to be the least reliable of the available methods.

The purpose of antibody assessment is to determine the quantity of Herpes virus antibodies in an individual's serum or CSF. Various methods have their own sensitivity, which is the percentage of HSE patients who are correctly detected, and they each have their own specificity, which indicates the risk of obtaining false positive results on the test. The complement fixation method for measuring the quantity of Herpes Simplex virus antibodies is generally used because it is inexpensive and quick. The Collaborative Study Group has found, however, that, judged by the standards of sensitivity and specificity, the three other types of assays noted are greatly preferable to the complement fixation method. The Group has found that 60% of the assays of HSE patients by the neutralizing antibody method show a titer rise, and that 62% of the immunoflourescence and hemagglutination assay methods show a titer rise. The complement fixation method, on the other hand, which was the only method employed in this case, picks up a titer rise in only one-half of all actual HSE cases. Moreover, the complement fixation method produces more false positives, which are titer rises in patients who do not have HSE.

Thus, with an overall accuracy of only 50%, the Collaborative Research Group's recent research has cast serious doubt on the efficacy and usefulness of the complement fixation method. But even using the better titer methods, and monitoring the serologic response over a six-week period, Dr. Whitley testified that only 60% of Herpes Simplex Encephalitis cases show a response. Even if all three of the better test methods are performed on a given patient who actually has HSE, the chance that at least one of the test results will be positive for HSE is only 75%; this means that one-fourth of the patients having HSE would show no titer rise even if each of the three best assay methods were employed in their case.

In sum, the lack of a titer rise in this case is clearly overshadowed by the questionable efficacy of this particular test as well as the rest of the clinical, neurodiagnostic and CSF picture. These other factors, particularly the findings of pronounced focality in the CAT scans, EEG, and perhaps brain scans, prove that the plaintiff falls into the category of the one-half of HSE patients whose antibody titers fail to rise by the complement fixation method.

Moreover, other antibody assay evidence in this case is strongly indicative of HSE. It has been found by Herpes researchers that a reliable predictor of HSE is shown by taking the ratio of the antibodies in the CSF compared to the antibodies in the blood serum of the patient. When the ratio of CSF antibodies over serum antibodies is less than 1:20, the test is indicative of HSE. The normal ratio of these numbers is approximately 100. In this case, Mrs. Stich's serum at Columbia contained a one to thirty-two ratio of antibodies. At the same time, the CSF antibody ratio was one to two. Thus, the overall ratio of CSF antibodies to serum antibodies is this case is sixteen, which is less than twenty, and therefore indicative of HSE. Accordingly, the overall results of the serological tests in this case are consistent with a case of HSE in which the complement fixation titers failed to rise, an event occurring in one-half of all confirmed HSE patients.

Plaintiffs' final argument regarding HSE is that the failure to isolate the offending virus calls into question such a diagnosis. Attempts by Riverview and Columbia to isolate the offending virus from the CSF, blood serum, stool and urine were unsuccessful. Several of the plaintiffs' experts stated that the failure to isolate an active virus from these substances rules out the diagnosis of HSE. As other testimony revealed, that view was incorrect.

As Dr. Price testified, the Herpes Simplex virus is characteristically not isolated from the CSF, the blood,

nor the stool of an HSE victim, such an event being "extraordinarily rare." The failure to isolate the offending virus in this case is characteristic of the clinical phenomenology of this disease; there simply is almost never an isolation of the Herpes Simplex virus in the various fluids (CSF, blood serum, stools) of a patient, even when the Herpes Simplex virus has been isolated in that patient's brain. And as Dr. Tsairis noted, failure to isolate the offending virus simply does not rule out a viral cause of Mrs. Stich's condition, according to current medical knowledge.

The physicians at Columbia Presbyterian Hospital had good reason not to perform a biopsy upon Mrs. Stich, even though they suspected that her problem was a viral encephalitis such as HSE. Mrs. Stich was transferred to Columbia Presbyterian Hospital for the purpose of a diagnosis on February 13, 1977, 79 days after her admission to Riverview Hospital. A biopsy at Columbia would probably have yielded no helpful information because it would have been extremely unlikely to find active Herpes Simplex virus after passage of that amount of time. This is so because, as Dr. Price testified, HSE is "a single phased disease where the virus causes infection, destruction of the [brain], and then, if the patient survives, the virus is cleared." Generally, a brain biopsy must be done as soon as possible to make a diagnosis for the effective use of antiviral drug therapy, with four weeks after onset regarded as the outside limit. The Columbia physicians recognized that a biopsy twelve weeks after onset of the disease could have no implications for Mrs. Stich's treatment, because it was too late to institute experimental drug therapy with ARA-A by that time in Mrs. Stich's disease process.

In summary, using the findings of the NIAID Collaborative Antiviral Study Group, which is recognized as the leading group of Herpes researchers in the world, I find strong factors in the present case predicting that HSE is the correct diagnosis, to the exclusion of any

other type of encephalitis, at a high level of confidence. I must further conclude that if a brain biopsy had been done during the acute phase of Mrs. Stich's illness, and if the procedure were performed at the affected brain site, positive evidence of the Herpes Simplex virus would have been found and the diagnosis of Herpes Simplex Encephalitis would have been confirmed.

There is no dispute in this case that the cause of viral encephalitis is a virus, and that no virus was present in the swine influenza vaccine. There is likewise no dispute that Herpes Simplex Encephalitis is caused by the Herpes Simplex virus, and not by any sort of vaccination. Therefore, in the absence of any causal relationship between the administration of the swine flu innoculation and Mrs. Stich's condition, I must grant judgment to the defendant.

**MRS. STICH'S CONDITION IS NOT "ADEM" OR POST-VACCINAL ENCEPHALITIS**

I find that the evidence in this case does not support either of plaintiffs' alternate diagnoses, acute disseminated encephalomyelitis ("ADEM") or post-vaccinal encephalitis.

ADEM is a diffuse disease of the white matter of the brain, often having the same clinical presentation as post-vaccinal encephalitis. ADEM is a disorder or a group of disorders which is mediated on an immune or allergic basis. The neurodiagnostic findings and the focalized presentation and sequelae of symptoms in this case are consistent with a focal viral encephalitis, and not with the diffuse disease of ADEM. The distinction between focal and diffuse involvement in the CAT scans, EEGs and brain scans is not an absolute distinction for the clinical neurologist, because involvement may be focal or multi-focal and occur in many distinct areas of the brain, and yet not be diffuse because it does not occur all over throughout the brain. In this case,

Mrs. Stich's involvement was at first focal, and then multi-focal as the viral encephalitis spread; the result was multi-focal involvement which eventually led to brain atrophy on a widespread basis.

The arguable presence of white matter involvement likewise does not distinguish this disease from Herpes Simplex Encephalitis, because the primary disease site was identified and reflected in gray matter disturbances, as discussed above. The eventual involvement of white matter was through edema which, as noted, was secondary to gray matter infection. Moreover, it must be recognized that HSE is a disease which affects both the gray and the white matter, while ADEM is a white matter disease. The presence of clear gray matter disturbances, as Dr. Poser has noted, argues strongly against ADEM.

The CAT scans in this case are not what one would expect in ADEM: the middle to higher cuts of the earlier CAT scans, which should be the site of ADEM, are normal and uninvolved. This lack of pathology in the higher cuts is evidence against ADEM. A donut-type lesion, which appeared in the February 17, 1977 CAT scan, affects the cortex of the brain (that is, the gray matter covering the brain), which is more consistent with HSE than ADEM. ADEM is not a cortical disease.

The plaintiffs have adduced no evidence to demonstrate that the CAT scans in this case are compatible with any series of known ADEM CAT scans. This disease, contrary to post-vaccinal encephalitis or ADEM, was highly localized; findings were consistently more pronounced on the left side of the body than the right. The eventual spread of the disease to involve opposite sides of the brain is the ordinary occurrence in HSE cases, where it is not unusual to have bilateral findings later in the illness.

ADEM is a very rare disease which has become even more rare. It is virtually unreported in the medical literature of CAT scans.

The physicians at Columbia, however, considered ADEM and were well aware of the parameters of that disease, but the consensus of the neurologists treating Mrs. Stich at Columbia was that her condition was not ADEM. ADEM or post-vaccinal encephalitis does not explain the profoundly focal characteristics, the devastating course of the disease and the neurodiagnostic findings in general. When compared with the strong support for viral encephalitis in general, and Herpes Simplex Encephalitis in particular, the support for ADEM and post-vaccinal encephalitis is insignificant.

Further, the history of vaccines fails to show a relationship between influenza vaccination and subsequent neurological disorders such as encephalomyelitis or encephalitis. Drs. Myer and Dyck testified that the overwhelming majority of scientists, neurologists, epidemiologists and other experts hold that there is no recognized or proven neurological complication of the use of influenza vaccinations other than GBS. Plaintiffs' evidence fails to establish the likelihood, as opposed to mere possibility, that the swine flu inoculation she received caused encephalitis. See *Jukubowski v. Minnesota Mining and Manufacturing*, 42 N.J. 177, 182 (1964).

The fact of a temporal association — that is, that an illness follows the vaccination in time — obviously does not mean that the immunization was the cause of the neurological illness. The temporal relationship between events is only the starting point, and not the finish line, for the epidemiological analysis which can best determine whether there is an association between the illness and the preceding vaccination. As Dr. Nathanson testified, the consensus of American epidemiologists does not associate any disease other than GBS with the swine flu vaccine.[26]

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26. In the medical literature, there are no reports that provide evidence associating non-GBS neurological diseases with the vaccine other than a single anecdotal report. The only epidemiological

## CONCLUSION

In light of my finding that Mrs. Stich's present condition is in all probability due to HSE, I think it is appropriate to note that I was quite impressed with the quality of testimony offered by Drs. Price, Whitely, Tsairis and Goodgold. Individually and collectively they offered a plausible and credible causal and diagnostic thesis which I have accepted. The records of The Neurological Institute of the Columbia Presbyterian Hospital described this as a "puzzling case." It is indeed. However, as one vested with the responsibility of adjudicating the case, I cannot take the luxury of adopting this description and walking out, so to speak. My obvious responsibility has been to consider all of the evidence in this case and to apply the law governing the case to the facts as I find them to be. Having done that, I am constrained to conclude that plaintiffs have failed to establish by a preponderance of the credible evidence that Mrs. Stich's condition is Guillian-Barre Syndrome. I further find that plaintiffs have also failed to demonstrate that the swine flu inoculation which was administered to Mrs. Stich was a substantial factor in causing Mrs. Stich's illness. I have instead concluded that Mrs. Stich's condition is, to a reasonable medical and legal certainty and by a preponderance of the credible evidence, Herpes Simplex Encephalitis of a viral etiology unrelated to the swine flu inoculation.

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Footnote — (Continued)
study conducted to determine the relationship between the swine flu vaccine and illnesses other than GBS was done by Dr. Henry Retailliau and Dr. Michael Hattwick and their associates at the Center for Disease Control. Their post swine flu surveillance did not support the hypotheses that encephalitis was related to the vaccine. No vaccine-associated encephalitis was found, despite the fact that the Retailliau-Hattwick Surveillance system had specifically sought reports of encephalitis.

An order in conformance with my determination has been entered by the court.

Dated: February 4, 1983

Harold A. Ackerman

HAROLD A. ACKERMAN, *U.S.D.J.*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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MIRIAM STICH and ERNEST STICH,
*Plaintiffs*

*v.*

UNITED STATES OF AMERICA,
*Defendant*

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(Civil Action No. 78-746)
Before: Hon. HAROLD A. ACKERMAN
Filed February 9, 1983

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**ORDER**
**FOR FINAL JUDGMENT**

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For the reasons set forth in the Court's opinion of even date,

It is on this 8th day of February, 1983;

ORDERED that judgment be entered in favor of defendant. No costs are awarded, due to the nature and complexity of this case.

Harold A. Ackerman

HAROLD A. ACKERMAN,
U.S.D.J.

FOR THE THIRD CIRCUIT

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No. 83-5343

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ERNEST STICH and MIRIAM STICH,
*Appellants*

v.

UNITED STATES OF AMERICA

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(D. C. Civil No. 78-0746)

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY — Trenton

Present: HUNTER and WEIS, *Circuit Judges*, and DUMBAULD, *District Judge**

**JUDGMENT**

This cause came on to be heard on the record from the United States District Court for the ——— District of New Jersey and was argued by counsel January 24, 1984.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court, entered April 4, 1983, be, and the same is hereby affirmed. Costs taxed against appellants.

ATTEST:

M. Elizabeth Ferguson

*Chief Deputy Clerk*

March 19, 1984

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* Honorable Edward Dumbauld, United States District Judge for the Western District of Pennsylvania, sitting by designation.

Certified as a true copy and issued in lieu of a formal mandate on May 1, 1984.

Test: M. Elizabeth Ferguson

Chief Deputy Clerk, United States Court of Appeals for the Third Circuit.

Costs taxed in favor of the USA as follows:

| | |
|---|---|
| Appendix . . | $694.60 |
| Brief . . . . . | $164.15 |
| TOTAL . . . . | $858.75 |

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 83-5343

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ERNEST STICH and MIRIAM STICH
*Appellants*

*v.*

UNITED STATES OF AMERICA

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**SUR PETITION FOR REHEARING**

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Present: SEITZ, *Chief Judge*, ALDISERT, ADAMS, GIBBONS, HUNTER, WEIS, GARTH, HIGGINBOTHAM, SLOVITER and BECKER, *Circuit Judges*

The petition for rehearing filed by

APPELLANTS

in the above entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

By the Court,

*Judge*

Dated: April 23, 1984

## STATUTES INVOLVED

National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1115, 42 U.S.C. §247b(j)-(1) (1976).

**National swine flu immunization program; establishment; limitations of program; quarterly reports to Congress; contracts for procurement of swine flu vaccine; authorization of funds**

(j)(1) The Secretary is authorized to establish, conduct, and support (by grant or contract) needed activities to carry out a national swine flu immunization program until August 1, 1977 (hereinafter in this section referred to as the "swine flu program"). The swine flu program shall be limited to the following:

(A) The development of a safe and effective swine flu vaccine.

(B) The preparation and procurement of such vaccine in sufficient quantities for the immunization of the population of the States.

(C) The making of grants to State health authorities to assist in meeting their costs in conducting or supporting, or both, programs to administer such vaccine to their populations, and the furnishing to State health authorities of sufficient quantities of such swine flu vaccine for such programs.

(D) The furnishing to Federal health authorities of appropriate quantities of such vaccine.

(E) The conduct and support of training of personal for immunization activities described in subparagraphs (C) and (D) of this paragraph and the conduct and support of research on the nature, cause, and effect of the influenza against which the swine flu vaccine is designed to immunize, the nature and effect of such vaccine, immunization

against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza.

(F) The development, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered. Such consultation shall be completed within two weeks after enactment of this Act, or by September 1, 1976, whichever is sooner. Such procedures shall include the information necessary to advise individuals with respect to their rights and remedies arising out of the administration of such vaccine.

(G) Such other activities as are necessary to implement the swine flu program.

(2) The Secretary shall submit quarterly reports to the Congress on the administration of the swine flu program. Each such report shall provide information on—

(A) the current supply of the swine flu vaccine to be used in the program;

(B) the number of persons inoculated with such vaccine since the last report was made under this paragraph and the immune status of the population;

(C) the amount of funds expended for the swine flu program by the United States, each State, and any other entity participating in the program and the costs of each such participant which are associated with the program, during the period with respect to which the report is made; and

(D) the epidemiology of influenza in the United States during such period.

(3) Any contract for procurement by the United States of swine flu vaccine from a manufacturer of such vaccine shall (notwithstanding any other provision of law) be subject to renegotiation to eliminate any profit realized from such procurement (except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/75 profit shall be allowed but limited to an amount not exceeding a reasonable profit), as determined pursuant to criteria prescribed by the Secretary, and the contract shall expressly so provide. Such criteria shall specify that any insurance premium amount which is included in the price of such procurement contract and which is refunded to the manufacturer under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the United States.

(4) No funds are authorized to be appropriated to carry out the activities of the swine flu program authorized in subparagraphs (A), (B), (D), (E), and (F) of paragraph (1) of this subsection in addition to the funds appropriated by Public Law 94-266.

**"Protection of agencies, organizations and individuals against nonnegligent liability arising from administration of swine flu immunization program; exclusive remedy; procedure for claims for personal injury or death; report to Congress on conduct of settlement and litigation activities**

(k)(1)(A) The Congress finds that—

(i) in order to achieve the participation in the program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine purchased and used in the swine flu program and to assure the availability of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negli-

gence to persons alleging personal injury or death arising out of the administration of such vaccine:

(ii) to provide such protection and to establish an orderly procedure for the prompt and equitable handling of claims by persons alleging such injury or death, it is necessary that an exclusive remedy for such claimants be provided against the United States because of its unique role in the initiation, planning, and administration of the swine flu program; and

(iii) in order to be prepared to meet the potential emergency of a swine flu epidemic, it is necessary that a procedure be instituted for the handling of claims by persons alleging such injury or death until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act.

(B) To—

(i) assure an orderly procedure for the prompt and equitable handling of any claim for personal injury or death arising out of the administration of such vaccine; and

(ii) achieve the participation in the swine flu program of (I) the manufacturers and distributors of the swine flu vaccine, (II) public and private agencies or organizations that provide inoculations without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and (III) medical and other health personnel who provide or assist in providing inoculations without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements.

it is the purpose of this subsection to establish a procedure under which all such claims will be asserted di-

rectly against the United States under section 1346(b) of title 28, and chapter 171 of such title (relating to tort claims procedure) except as otherwise specifically provided in this subsection.

(2)(A) The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(b) and chapter 171, except that—

(i) the liability of the United States arising out of the act or omission of a program participant may be based on the theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty;

(ii) the exceptions specified in section 2680(a) of title 28, shall not apply in an action based upon the act or omission of a program participant; and

(iii) notwithstanding section 2401(b) of title 28, if a civil action or proceeding for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program is brought within two years of the date of the administration of such vaccine and is dimissed because the plaintiff in such action or proceeding did not file an administrative claim with respect to such injury or death as required by such chapter 171, the plaintiff in such action or proceeding shall have 30 days from the date of such dismissal or two years from the date the claim arose, whichever is later, in which to file such administrative claim.

(B) For purposes of this subsection, the term "program participant" as to any particular claim means the manufacturer or distributor of the swine flu vaccine used in an inoculation under the swine flu program, the public or private agency or organization that provided an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and the medical and other health personnel who provided or assisted in providing an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements.

(3) The remedy against the United States prescribed by paragraph (2) of this subsection for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death against any employee of the Government (as defined in section 2671 of title 28) or program participant whose act of omission gave rise to the claim.

(4) The Attorney General shall defend any civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant (or any liability insurer thereof) based upon a claim alleging personal injury or death arising out of the administration of vaccine under the swine flu program. Any such person against whom such civil action or proceeding is brought shall deliver all process served upon him (or an attested true copy thereof) to whoever is designated by the Secretary to receive such papers, and such person shall promptly furnish copies of the pleadings and process therein to the United States attorney for the district embracing the

place wherein the civil action or proceeding is brought, to the Attorney General, and to the Secretary.

(5)(A) Upon certification by the Attorney General that a civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant is based upon a claim alleging personal injury or death, arising out of the administration of vaccine under the swine flu program, such action or proceeding shall be deemed an action against the United States under the provisions of title 28, and all references thereto. If such action or proceeding is brought in a district court of the United States, then upon such certification the United States shall be substituted as the party defendant.

(B) Upon a certification by the Attorney General under subparagraph (A) of this paragraph with respect to a civil action or proceeding commenced in a State court, such action or proceeding shall be removed, without bond at any time before trial, by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and be deemed an action brought against the United States under the provisions of title 28, and all references thereto; and the United States shall be substituted as the party defendant. The certification of the Attorney General with respect to program participant status shall conclusively establish such status for purposes of such initial removal. Should a district court of the United States determine on a hearing on a motion to remand held before a trial on the merits that an action or proceeding is not one to which this subsection applies, the case shall be remanded to the State court.

(C) Where an action or proceeding under this subsection is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the action or proceeding shall be dismissed, but in

that event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this subsection.

(6) A program participant shall cooperate with the United States in the processing or defense of a claim or suit under such section 1346(b) and chapter 171 based upon alleged acts or omissions of the program participant. Upon the motion of the United States or any other party, the status as a program participant shall be revoked by the district court of the United States upon finding that the program participant has failed to so cooperate, and the court shall substitute such former participant as the party defendant in place of the United States and, upon motion, remand any such suit to the court in which it was instituted.

(7) Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation, resulting from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract with the United States in connection with the program or from any negligent conduct on the part of any program participant in carrying out any obigation or responsibility in connection with the swine flu program. The United States may maintain such action against such program participant in the district court of the United States in which such program participant resides or has its principal place of business.

(8) Within one year of August 12, 1976, and semiannually thereafter, the Secretary shall submit to the Congress a report on the conduct of settlement and litigation activities under this subsection, specifying the

number, value, nature, and status of all claims made thereunder, including the status of claims for recovery made under paragraph (7) of this subsection and a detailed statement of the reasons for not seeking such recovery.

**Definitions relating to the swine flu immunization program**

(*l*) For the purposes of subsections (j) and (k) of this section—

(1) the phrase "arising out of the administration" with reference to a claim for personal injury or death under the swine flu program includes a claim with respect to the manufacture or distribution of such vaccine in connection with the provision of an inoculation using such vaccine under the swine flu program;

(2) the term "State" includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands; and

(3) the term "swine flu vaccine" means the vaccine against the strain of influenza virus known as influenza A/New Jersey/76 (Hsw 1N1), or a combination of such vaccine and the vaccine against the strain of influenza virus known as influenza A/Victoria/75

* * * *

Act Aug. 12, 1976, P. L. 94-380, §3, 90 Stat. 1118, provided: "The Secretary of Health, Education, and Welfare shall conduct, or provide for the conduct of, a study of the scope and extent of liability for personal injuries or death arising out of immunization programs and of alternative approaches to providing protection against such liability (including a compensation system) for such injuries. Within one year of the date of the enactment of this Act [enacted Aug. 12, 1976], the Secretary shall report to the Congress the findings of such study and such recommendations for legislation (including proposed drafts to carry out such recommendations) as the Secretary deems appropriate."

## RELEVANT SECTIONS OF THE FEDERAL TORT CLAIMS ACT

**28 U.S.C. §1346. United States as defendant**

* * * *

(b) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

* * * *

**28 U.S.C. §2402. Jury trial in actions against United States.**

Any action against the United States under section 1346 shall be tried by the court without a jury, except that any action against the United States under section 1346(a) (1) shall, at the request of either party to such action, be tried by the court with a jury.

**28 U.S.C. §2674. Liability of United States**

The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.

If, however, in any case wherein death was caused, the law of the place where the act or omission complained of occurred provides, or has been construed to provide, for damages only punitive in nature, the United States shall be liable for actual or compensatory damages, measured by the pecuniary injuries resulting from such death to the persons respectively, for whose benefit the action was brought, in lieu thereof.

**28 U.S.C. §2675. Disposition by federal agency as prerequisite; evidence**

(a) An action shall not be instituted upon a claim against the United States for money damages for injury or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, unless the claimant shall have first presented the claim to the appropriate Federal agency and his claim shall have been finally denied by the agency in writing and sent by certified or registered mail. The failure of an agency to make final disposition of a claim within six months after it is filed shall, at the option of the claimant any time thereafter, be deemed a final denial of the claim for purposes of this section. The provisions of this subsection shall not apply to such claims as may be asserted under the Federal Rules of Civil Procedure by third party complaint, cross-claim, or counterclaim.

(b) Action under this section shall not be instituted for any sum in excess of the amount of the claim presented to the federal agency, except where the increased amount is based upon newly discovered evidence not reasonably discoverable at the time of presenting the claim to the federal agency, or upon allegation and proof of intervening facts, relating to the amount of the claim.

(c) Disposition of any claim by the Attorney General or other head of a federal agency shall not be competent evidence of liability or amount of damages.

**28 U.S.C. §2680. Exceptions**

The provisions of this chapter and section 1346(b) of this title shall not apply to—

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

* * * *

**Federal Rule of Civil Procedure 26(e)**

**(e) Supplementation of Responses.** A party who has responded to a request for discovery with a response that was complete when made is under no duty to supplement his response to include information thereafter acquired, except as follows:

(1) A party is under a duty seasonably to supplement his response with respect to any question directly addressed to (A) the identity and location of persons having knowledge of discoverable matters, and (B) the identity of each person expected to be called as an expert witness at trial, the subject matter on which he is expected to testify, and the substance of his testimony.

(2) A party is under a duty seasonably to amend a prior response if he obtains information upon the basis of which (A) he knows that the response was incorrect when made, or (B) he knows that the response though correct when made is no longer true and the circumstances are such that a failure to amend the response is in substance a knowing concealment.

(3) A duty to supplement responses may be imposed by order of the court, agreement of the parties, or at any time prior to trial through new requests for supplementation of prior responses.

## OTHER MATERIALS

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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CERTAINTEED CORPORATION : Civil Action

*v.* :

LEXINGTON INSURANCE COMPANY : No. 82-1668

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### MEMORANDUM OPINION AND ORDER

VanARTSDALEN, *J.* December 21, 1983

Two furnaces located at plaintiff's fiberglass manufacturing plant in Wichita Falls, Texas, were extensively damaged. Plaintiff contends that a policy of insurance issued by defendant insured plaintiff against the loss. Defendant denies coverage on the ground that there was no "accident" as contemplated by the contract of insurance. Presently before the court are defendant's motions (1) to preclude the testimony of plaintiff's expert; (2) to strike supplemental answers of plaintiff; and (3) for summary judgment.[1] For the reasons stated herein, the motions will be denied.

Defendant Lexington Insurance Company's (Lexington) primary ground for seeking to preclude plain-

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1. It is evident that while defendant has filed three separate motions the disposition of two of them depends in large measure upon the outcome of the third motion. The critical motion involved is the motion to exclude plaintiff's expert witness. The supplemental answers sought to be stricken in the motion to strike are the answers relating to the expert. Thus, the outcome of the motion to exclude the expert's testimony basically controls the outcome of this motion. Similarly, the motion for summary judgment depends upon the motion to exclude the expert. Considering this circuit's strict guidelines concerning summary judgment, should I decide the expert may testify, there would be genuine issues of material fact for trial.

tiff's expert from testifying is that plaintiff's counsel did not notify defendant that this particular expert would be testifying until a month after the discovery deadline set by the court had passed. The record establishes that the original discovery deadline set in this case was December 15, 1982. Twice by agreement of counsel and once upon motion of defendant the discovery was reset. By order dated August 16, 1983, I set a discovery deadline of September 30, 1983, with pretrial memoranda to be filed by October 14, 1983.

As of September 30, 1983, plaintiff had not responded to Lexington's outstanding expert witness interrogatories. Evidently plaintiff retained Mr. Myron Smith sometime in late September. Mr. Smith performed an inspection of the furnaces sometime in early October. Thereafter, he communicated the results of his findings to plaintiff's counsel. Apparently pleased with those findings, plaintiff's counsel notified defendant's counsel by phone, on or about October 28, 1983, that Mr. Smith was to be called as an expert witness at trial. On October 31, 1983, more than two weeks late, plaintiff filed its pretrial memorandum identified Mr. Smith as an expert and stating that the expert was prepared to give an opinion that the alleged "accidents" were caused by explosions in the furnaces. Defendant filed the instant motions in response.

Defendant objects to the naming of an expert one month after the close of discovery. Lexington argues that "[i]t is improper and unfair" for the plaintiff at this late date "to put forth a wholly new theory of causation." Finally, defendant asserts that "[i]f the Courts[sic] Orders are to have any meaning, they must be subject to reasonable enforcement." As to this final point, I agree absolutely with defendant's assertion. However, I am constrained by the holdings of this circuit, whether I agree with them or not. There is no doubt that application of those standards enunciated by the Court of Ap-

peals for the Third Circuit leads to the conclusion that the motions must be denied.

There is a growing discovery problem on the late disclosure of the identity of expert witnesses. In four different cases presently before me, the exact same issue has arisen in the last month.[2] In all four instances, one side sought to have one or more expert witnesses precluded from testifying at trial because the expert was not identified until after the court's discovery deadlines had passed. Because I perceive this to be an increasingly serious problem in the smooth administration of justice, I feel compelled to add some words of caution as to the present situation confronting the judges of this court.

A seminal case in this circuit controlling the excluding of witnesses for failure to identify such witnesses within the time set by the court's order is *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977). In *Meyers*, the district court had excluded two key witnesses offered by Meyers on the ground that they were not listed in plaintiff's pretrial memorandum. *Id.* at 903. The court had directed that all discovery be completed by January 30, 1976. Plaintiff was to file his pretrial memorandum, with a list of witnesses, by January 15, 1976. Trial was scheduled for March 17, 1976. On February 26, 1976, "plaintiff evidently having learned of potential new fact witnesses" informed defense counsel he wished to supplement the pretrial memorandum. *Id.* Defendant made no effort to contact plaintiff's counsel or depose the proffered witnesses, although counsel complained of prejudice and surprise in a letter to the court.

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2. Aside from the present case, the issue arose in *Karas v. Jackson*, No. 81-4727 (E.D. Pa. November 30, 1983); *Borel v. Hafer*, No. 81-388 (E.D. Pa. December 21, 1983) (filed contemporaneously with this opinion); *National Rolling Mills Co. v. Liberty Mutual Insurance Co.*, No. 82-4512 (issue raised but withdrawn by a stipulation signed by the court which extended discovery deadline).

At trial the judge refused to allow plaintiff to call these witnesses. The court of appeals found an abuse of discretion despite the recognition that a trial court's decision to exclude evidence because of the failure of counsel to adhere to a pretrial order will not be disturbed on appeal absent a clear abuse of discretion. The court stated that there were four basic considerations underlying this question:

> (1) the prejudice or surprise in fact of the party against whom the excluded witness would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court's order.

*Meyers*, 559 F.2d at 904-05. Applying these considerations in *Meyers*, the court of appeals "[was] constrained to conclude that the district court abused its discretion in excluding [the witnesses]." *Id.* at 905.

The court of appeals has repeatedly reaffirmed the holding in *Meyers*. Perhaps the best summary of the court's position is found in *De Marines v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1202 (3d Cir. 1978), where the court stated, "we are sensitive to the district court's need to maintain control over the discovery process and the fair, orderly presentation of evidence. Yet, exclusion of evidence is a drastic sanction, . . ., which must pass the strict *Meyers* test to be upheld."

Canvassing the relevant decisions may be helpful. Research discloses that there is not a single reported case in this circuit where a district judge's exclusion of a key fact witness or expert witness was upheld. In one instance, the exclusion of a rebuttal witness was upheld. *Franklin Music v. American Broadcasting Companies*, 616 F.2d 528, 539-40 (3d Cir. 1979). In another case, the exclusion of the findings of a study not contained in

the pretrial memorandum, offered by an expert witness, was upheld. *Coleco Industries, Inc. v. Berman*, 567 F.2d 569, 576 (3d Cir. 1977), *cert. denied*, 435 U.S. 830 (1979). In both cases the court stated that exclusion of evidence was disfavored but found facts justifying the district court's decision.

In contrast, research discloses three cases in this circuit in which the district court was found to have abused its discretion by excluding evidence, *Joy Manufacturing Co. v. Sola Basic Industries*, 697 F.2d 104 (3d Cir. 1982) (district court abused its discretion in not allowing amendment of pretrial narrative); *De Marines*, 580 F.2d at 1202 (district court abused discretion in excluding testimony of medical expert on subject not included in writing submitted to the court); *Meyers*, 559 F.2d at 904-05 (district court abused discretion in excluding key fact witnesses not named in pretrial memorandum). Also, there are two appellate cases in which permitting testimony not included in pretrial memoranda was upheld: *Berroyer v. Hertz*, 672 F.2d 334 (3d Cir. 1982) (district court did not err in permitting witness not named on pretrial list to testify); *Keegan v. Anchor Inns, Inc.*, 606 F.2d 35 (3d Cir. 1979) (no merit in argument that failure to exclude expert testimony for counsel's failure to provide timely answers to expert interrogatories was abuse of discretion). Research also discloses three district court cases in which experts were permitted to testify despite the fact that they were not listed on pretrial memorandum. *Mc Elroy v. Cessna Aircraft Co.*, 506 F. Supp. 1211 (W.D. Pa. 1981); *Skill v. Martinez*, 91 F.R.D. 498 (D.N.J. 1981), *aff'd*, 677 F.2d 368 (3d Cir. 1982); *Dychalo v. Copperloy Corp.*, 78 F.R.D. 146 (E.D. Pa.), *aff'd mem.*, 588 F.2d 820 (3d Cir. 1978).

In order for the trial judge to retain control of the litigation's orderly progression toward trial, he should be able to *set* and *enforce* pretrial deadlines. The more severe the sanction the greater the probability of compli-

ance. Short of outright dismissal, the strictest sanction available is exclusion of evidence and witnesses. Yet, this circuit strongly disfavors exclusion for failure to timely follow pretrial orders. Thus, there is a clash between the two policies. Heretofore this circuit has resolved the issue in favor of a policy discouraging exclusion of evidence by requiring strict compliance with the *Meyers* test. The present case is typical of those cases in which a motion is made to exclude an expert witness for failure to identify the expert before the close of discovery. As such, the application of the *Meyers* standard to the facts of this case is indicative of the outcome in most such cases.

The present case has not been listed for a specific trial date. In light of this, it is very difficult for defendant Lexington to argue either the prejudice or surprise in fact required by *Meyers*. An expert who testifies on behalf of a plaintiff will normally be expected to advance a theory consistent with plaintiff's claim. Thus, a defendant can seldom successfully claim "surprise." Plaintiff Certainteed asserts that defendant is not "surprised." In a general sense that is always true. However, it is the facts known and opinions held by the expert that the adverse party is interested in obtaining and which the Federal Rules allow a party to discover. *See* Fed. R. Civ. P. 26(b)(4).

The prejudice requirement of *Meyers* will also rarely be met in the case of an expert witness. In this action, as in most cases where the issue arises, the case had not been listed for a specific trial date at the time that discovery was due. Thus, there remains time in which the deposition of the expert can be taken and there is little or no prejudice in that sense. However, the "prejudice" involved with experts is not the same type as that contemplated in *Meyers*, where fact witnesses were excluded. When a party is allowed to identify an expert after discovery has closed, even though trial has not been set and the expert could be deposed, there is "prejudice" involved.

First, it allows one side to gain a possible tactical advantage. If the adverse party complies with the discovery deadlines and timely submits its expert's report, then the delinquent party can, at its leisure, submit its expert's report thereafter fully aware that exclusion will rarely be granted for missing a deadline. Enforcing the discovery deadline would prevent attorneys from playing "cat and mouse" with respect to whose report should be produced first.

Second, the party waiting for the expert's report or answers to interrogatories is forced to delay preparing the case for trial. When a fact witness is produced just before trial, the prejudice can be ameliorated by taking his deposition and offering rebuttal testimony. While this may also be true to a limited extent with respect to experts, the technical nature of the evidence, often makes the task difficult.

Third, there is "prejudice" in the sense that the trial court loses, in large measure, the ability to control the orderly administration of the case. If a trial judge cannot set and enforce deadlines, there is no way to insure the smooth flow of a large number of cases.

There are, of course, other sanctions which can be imposed which are less drastic than exclusion, such as taxing of costs to the delinquent party or attorney. However, such other remedies are largely toothless and ineffective. Many counsel will only be prodded to timely action when facted with the possibility of going to trial without an expert witness.

Although exclusion may appear to be a drastic sanction, such is largely a matter of perspective. In the present case, for instance, the complaint was filed on April 15, 1982. The original discovery deadline of December 15, 1982, was postponed three times until September 30, 1983. Thus, plaintiff had over seventeen months to identify an expert. Of course, viewing the penalty alone may lead one to believe the sanction is drastic but, when viewed in the overall context, the pen-

alty would be appropriate to curb the infraction. Where the failure to identify an expert before the close of discovery is justified, no sanction need be imposed. The tardy party, however, should bear the burden of proof and the motion should be made *before* the discovery deadline.

The third of the *Meyers*' considerations involves the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court. As stated earlier, with respect to expert witnesses, this consideration, as presently formulated, is rarely applicable. This is so because at the time the discovery deadline expires the case will probably not be listed for trial. Thus, there is usually time to schedule the expert's deposition before trial, although it is often inconvenient. This concern misses the point in the case of experts. The depositions of experts, which should be before discovery closes, have to be rescheduled before trial. This causes a serious problem. Both sides should be prepared for trial after the date on which discovery closes and they should not, in the time before trial, be adjusting counsels' and the court's busy schedules to "fit" in an expert's deposition. Delay of the trial, sometimes severe, is inevitable.

The final *Meyers*' consideration, bad faith or willfulness in failing to comply with the court's order, is difficult to establish. There is little question that as presently applied this concern only attaches to egregious cases. Regardless of the type of witness, exclusion would be justified under such circumstances. However, counsel will rarely dare to draw the court's ire with such flagrant conduct, as to be obvious. More likely is a scenario where counsel can disregard court-imposed deadlines, without either the court or the opposing party being able to prove bad faith or willfulness. In all four cases which have recently raised this issue, there is absolutely no indication that the deadlines were missed due to any bad

faith by counsel. Yet, the fact is that the deadlines were missed, necessitating numerous problems and delays.

The Court of Appeals for the Eleventh Circuit recently upheld a district court's exclusion of three expert witnesses for the defendant because they were not identified until after the discovery deadline. *Port Terminal and Warehousing v. John S. James Co.*, 695 F.2d 1328 (11th Cir. 1983). The district court in its order stated in part:

> This is not a case in which it is argued that witnesses came to light only at the last moment. These proposed witnesses are experts. Their status as witnesses depends on counsel's decision alone and not on any actual relationship to the underlying controversy. . . . The underlying data has been available to defendants for months. . . .The defendants here were entirely in control of the designation of experts. No inadvertent discovery of an important fact witness was involved. The issues have been known for months.

*Id.* at 1335. Thus, the eleventh circuit noted a clear distinction between expert witnesses and fact witnesses. Unfortunately, however, there is no such distinction recognized for expert witnesses under the *Meyers* rule.

The recent amendment to Federal Rule of Civil Procedure 16, mandating pretrial conferences and early establishing of scheduling deadlines was expressly intended to require district judges to establish "early and continuing control so that the case will not be protracted because of lack of management." Fed. R. Civ. P. 16(a) (2). A scheduling order that "limits the time . . . (3) to complete discovery" must be entered. Fed. R. Civ. P. 16(b) (3). The order "shall control the subsequent course of the action unless modified by a subsequent order." Fed. R. Civ. P. 16(e). Among permissible sanctions, the trial judge on his own motion may impose any of the sanctions provided in Fed. R. Civ. P. 37(b)(2)(B), (C), (D).

Despite all of the good intentions of Federal Rule of Civil Procedure 16, so long as the rule of *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977), remains the law of this Circuit, the district court judges will remain unable to effectively carry out the intent of Federal Rule of Civil Procedure 16. Regretfully, defendant's motions must be denied. However, defendant will be permitted to depose plaintiff's expert witness, and, if after deposing such witness defendant seeks to obtain an expert witness in defense, defendant may do so. An order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| | | |
|---|---|---|
| Certainteed Corporation | : | Civil Action |
| *v.* | : | |
| Lexington Insurance Company | : | No. 82-1668 |

**ORDER**

It is ordered as follows:

1. Defendant's motion to preclude the testimony of Myron Smith as an expert witness is denied;

2. Defendant's motion to strike the supplemental answers of the plaintiff to the second set of interrogatories of the defendant is denied;

3. Defendant's motion for summary judgment is denied;

4. Defendant may take the oral deposition of the expert witness, Myron Smith, within thirty (30) days from the date of this order;

5. Defendant may, within sixty (60) days of this order, identify any additional expert witnesses it intends to utilize at trial and provide supplemental answers to any

discovery heretofore filed to the extent appropriate upon the taking of the deposition of Myron Smith;

6. Each party shall pay its own costs of preparing and filing the present motions.

BY THE COURT:

Office - Supreme Court, U.S.
FILED
SEP 22 1984
ALEXANDER L. STEVAS,
CLERK

No. 84-109 (2)

# In the Supreme Court of the United States

OCTOBER TERM, 1984

ERNEST STICH, ET UX., PETITIONERS

*v.*

UNITED STATES OF AMERICA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT*

## MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

REX E. LEE
*Solicitor General*
*Department of Justice*
*Washington, D.C. 20530*
*(202) 633-2217*

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# In the Supreme Court of the United States

OCTOBER TERM, 1984

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No. 84-109

ERNEST STICH, ET UX., PETITIONERS

*v.*

UNITED STATES OF AMERICA

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*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT*

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**MEMORANDUM FOR THE UNITED STATES IN OPPOSITION**

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Petitioners seek review of the decision of the court of appeals that the government's use of a "surprise" expert witness and other alleged abusive tactics during the trial of their case arising under the National Swine Flu Immunization Program of 1976 (Swine Flu Act), Pub. L. No. 94-380, 90 Stat. 1113 *et seq.*, did not affect the district court's finding that their injuries were not caused by swine flu vaccine.

1. The Swine Flu Immunization Program was initiated in 1976 as an effort by the federal government to immunize a large portion of the population of the United States in order to prevent a potential influenza epidemic. § 2, 90 Stat. 1113. Because of the risk that some people would react adversely to the vaccine, Congress did not force anyone to participate in the program; it was created as a purely voluntary program, both for those providing the vaccine and

those receiving it. 122 Cong. Rec. 20280 (1976) (remarks of Sen. Javits). To encourage drug manufacturers to supply the vaccine, Congress provided that the United States under the Federal Tort Claims Act, 28 U.S.C. 1346, 2671 *et seq.*, would assume all of the liability of program participants that otherwise would have existed under applicable state law. § 2, 90 Stat. 1115.

Petitioner Miriam Stich[1] received a swine flu vaccination as part of the federal government's inoculation program on November 18, 1976. Nine days later she began experiencing muscle aches, a headache, fever and general malaise. Her condition deteriorated and on November 27, 1976, she was admitted to a hospital in Red Bank, New Jersey (Pet. App. A14). At that time she was unconscious and having convulsions. Petitioner's treating physician diagnosed her condition as "meningo-encephalitis of unknown etiology" (*id.* at A15). Petitioner has been transferred to several hospitals since then and with extensive therapy her condition has improved to some extent. Nevertheless, petitioner is still hospitalized; she remains disoriented and her speech is largely unintelligible (*id.* at A4).

2. Petitioners filed suit under the Swine Flu Act, § 2, 90 Stat. 1115, against the United States in the United States District Court for the District of New Jersey, alleging that petitioner had contracted Guillian-Barre Syndrome (GBS) or some other disease of the central or peripheral nervous system that was causally related to the swine flu vaccine she received in November 1976 (Pet. App. A2). Petitioners' action, along with several hundred other suits, was transferred by the Judicial Panel on Multi-District Litigation to

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[1]The other petitioner is Mrs. Stich's husband, who brought suit derivatively, claiming loss of consortium and of his wife's services (Pet. App. A11). For simplicity, "petitioner" will be used to refer to Mrs. Stich.

the United States District Court for the District of Columbia for consolidated pre-trial proceedings pursuant to 28 U.S.C. 1407. The final pre-trial order provided that if petitioner established that she had contracted GBS, liability would be conclusively presumed. If, however, a disease other than GBS were proved, petitioner would have the additional burden of establishing negligence or some other basis of liability (Pet. App. A4, A5). After the conclusion of the consolidated pre-trial proceedings, the case was transferred back to the District of New Jersey for trial.

After a bench trial, the district court entered judgment for the United States (Pet. App. A10-A64). Based on an exhaustive analysis of the diagnostic symptoms for GBS, the district court found that petitioner had failed to establish by a preponderance of the evidence that her illness was GBS or any other condition recognized as having been caused by the swine flu vaccine (*id.* at A21-A32). The court concluded instead that petitioner suffered from Herpes Simplex Encephalitis (HSE), which is a viral condition that causes an inflammation of the brain and is not caused by swine flu vaccine (*id.* at A42-A60).

The court of appeals affirmed (Pet. App. A1-A9). Petitioners raised several issues on appeal, but the court of appeals disposed of all but one without discussion (*id.* at A5 n.2). The court of appeals rejected petitioners' claim that the district court erred when it permitted Dr. Richard Whitley to testify as a "surprise" expert on behalf of the government concerning an article that he had authored just before trial on the subject of HSE and its symptoms. The court noted that the government had not deliberately concealed the article from petitioners; the expert had not finished it until shortly before he was scheduled to testify. Moreover, the court found that "[petitioners'] claim of surprise is attenuated by the fact that they had long been aware of several articles written by Dr. Whitley that relied on essentially the

same data base, but had not requested discovery of that data" (*id.* at A7 (footnote omitted)). The court of appeals also pointed out that the district court was justifiably concerned that granting petitioners a continuance to examine the article or its data would unduly delay the trial, and it observed that petitioners did little to mitigate this problem: "Although [petitioners] had had the new article for a week before Dr. Whitley was scheduled to testify, they waited until [he] was on the stand and testifying to make their discovery request" (*ibid.*).

Finally, the court of appeals concluded that "a fair reading of the district court's opinion suggests that the judge did not rely on Dr. Whitley's article or testimony in deciding that [petitioner] did not have GBS * * * [;] [i]t appears that the judge relied on the contested article and testimony only in concluding that [petitioner] had HSE—a conclusion unnecessary to the judge's decision that [petitioners] failed to carry their burden of proving that [petitioner's] illness was caused by the Swine Flu shot" (Pet. App. A8 n.6).[2]

3. Petitioners' principal contention (Pet. 16-17) is that the court of appeals erred in not finding that the district court abused its discretion in failing to sustain their objection to Dr. Whitley's expert testimony. Petitioners do not demonstrate, however, how the court of appeals erred in its application of the abuse of discretion standard to the facts of this case. Instead, they point (Pet. 16) to an alleged conflict among the circuits regarding the issue of the admissibility of "late-emerging expert testimony." Petitioners

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[2]The court of appeals also held that "[w]hile there is some force" to petitioners' argument that the district court erred in failing to grant them the right, under Rule 1006 of the Federal Rules of Evidence, to discover the underlying data summarized in "Table 4" of the article, "[petitioners] waived it by failing to raise it below in a specific and timely fashion" (Pet. App. A9).

assert (Pet. 16-17) that many other courts of appeals have reversed on the basis that late emerging testimony was introduced, but the Third Circuit allegedly has refused to hold that such expert testimony is ever erroneously admitted, and that the decision below is representative of the circuit's improper practice.

Even if petitioners' characterization of Third Circuit law were correct, and they cite no decision of that court as announcing any such blanket rule concerning expert testimony, the district court's decision was not based on a standard weighed heavily against exclusion of "late-emerging" testimony. Instead, it was "predicated on a balancing of prejudice and unfair surprise against materiality and delay in the litigation" (Pet. App. A9). The decision of the court of appeals concluded that petitioners failed to demonstrate that the district court abused its discretion in applying that balancing test to the facts of this case. Such a fact-bound holding clearly does not warrant review by this Court.

Moreover, any error committed by the district court in failing to exclude Dr. Whitley's testimony or in failing to give petitioners additional time to study Dr. Whitley's article was harmless. As the court of appeals stated, "a fair reading of the district court's opinion suggests" that the district court relied upon Dr. Whitley's testimony only in support of its conclusion that petitioner had HSE.[3] But that

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[3]After an exhaustive review of the medical evidence and without reference to the disputed expert testimony, the district court concluded that petitioner "did not exhibit the symptoms necessary to a diagnosis of GBS" (Pet. App. A8 n.6, A16-A42), acute disseminated encephalomyelitis (ADEM) or post-vaccinal encephalitis (*id.* at A60-A62). Relying heavily on the diagnostic guides set forth in Dr. Whitley's article, the district court concluded that petitioner's condition was HSE (*id.* at A49). Since petitioners failed to meet their burden of showing that petitioner's illness was GBS or any other disease associated with the swine flu vaccine, petitioners would not have prevailed even without the finding on HSE.

conclusion was unnecessary to the critical finding that petitioners' evidence was insufficient to prove that petitioner suffers from GBS or any other disease caused by the swine flu vaccine (Pet. App. A8 n.6). Accordingly, this case is an inappropriate vehicle for resolving any issues concerning the standards for admissibility of expert testimony.[4]

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

REX E. LEE
*Solicitor General*

SEPTEMBER 1984

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[4]Petitioners also contend (Pet. 12-13) that this Court should review this case because the government's conduct at trial evidenced a breach of its duty to administer claims under the Swine Flu Act fairly. But Congress decided to use the adversary, judicial process to resolve claims based on the inoculation of swine flu vaccine; it could hardly have assumed that the government would not defend against questionable claims vigorously. Thus, the issue in swine flu vaccine cases is the same as in any case where abusive trial tactics are alleged—whether the litigant's conduct unfairly affected the ability of the trier of fact to reach a decision. Petitioners have not shown how the alleged abuses tainted the district court's ultimate finding that petitioner did not have GBS or any other disease associated with the swine flu vaccine. The court of appeals rejected petitioners' contentions in this regard as "meritless" (Pet. App. A5 n.2). That fact-bound determination, which affects only petitioners, does not warrant further review.

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No. 84-109

IN THE

# SUPREME COURT OF THE UNITED STATES

October Term, 1984

ERNEST STICH and MIRIAM STICH,
*Petitioners*

*v.*

UNITED STATES OF AMERICA,
*Respondent*

## ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

## PETITIONERS' REPLY TO MEMORANDUM FOR THE UNITED STATES IN OPPOSITION TO PETITION

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The government's memorandum fails to address the compelling and overriding reason why this Court should review this case: if this Court leaves unredressed the denial of the Stichs' basic right to a fair federal trial of their swine flu claim against the government, public confidence in the fairness and integrity of government-sponsored public health programs will be destroyed, and voluntary participation in such programs adversely affected.

Instead, echoing the flawed analysis of the court of appeals, the government jumps to the merits of the case in its effort to discourage review by this Court. The government's arguments only serve to bring into sharper focus the need for review.

1. The government is simply wrong in stating (Memorandum, p. 6) that the district court's decision to allow the surprise Whitley testimony and article — the key government evidence to support its HSE defense — was harmless error. The decision was prejudicial in the extreme: the district court relied on the Whitley evidence in making the pivotal finding that the Stichs had not met their burden of proving that Mrs. Stich had contracted post-vaccinal encephalitis, a disease, like GBS, compensable under the Swine Flu Act. *The district court found that evidentiary support for post-vaccinal encephalitis was insufficient "[w]hen compared with the strong support for viral encephalitis in general, and Herpes Simplex Encephalitis in particular. . . ."* (A 62) (emphasis added). Were it not for the Whitley HSE evidence, an entirely different evidentiary picture would have been presented, and the Stichs would have prevailed. Whitley himself admitted that, if HSE were excluded, *the next most likely diagnosis for Mrs. Stich was post-vaccinal encephalitis.*

For the same reason, the government is wrong in its myopic contention that Petitioners failed to show how the discovery abuses tainted the district court's ultimate finding that Mrs. Stich did not have a disease associated with the swine flu vaccine. (Memorandum, p. 6, n.4).

The government's interference with one of Petitioners' key witnesses (who would have testified that Mrs. Stich was not suffering from HSE) and its withholding of crucial epidemiological data drastically altered the constellation of trial evidence. It is therefore pure sophistry to suggest, as the government does here, that the abuses had no effect on the outcome of the trial.

2. Review by this Court is imperative to effectuate the mandate of Federal Rule of Civil Procedure 26(e) and to protect a litigant's right to cross-examination of an expert, as guaranteed by Federal Rule of Civil Procedure 26(b)(4). At trial, the court denied Petitioners' request to examine crucial epidemiological data underlying the Whitley article and/or to exclude Whitley from testifying. In reaching that determination, the trial court relied on Federal Rule of Evidence 403. As the court of appeals acknowledged, Rule 403 was the wrong legal standard to have applied to what was, in effect, a mid-trial discovery request necessitated by the government's failure to disclose Whitley's surprise change in testimony in flagrant violation of Rule 26(e). Nonetheless, the court of appeals excused the trial court's error and announced that the legal test under Federal Rule of Evidence 403 for exclusion of trial evidence otherwise relevant is the same as the test under Rule 26 for the discovery of facts underlying an expert opinion, even where such facts are crucial for the meaningful preparation of cross-examination. (A-8).

This ruling is not, as the government suggests (Memorandum, p.5), a routine matter unworthy of review. This ruling has grave implications: it eviscerates the mandate of Rule 26(e) and the right to prepare effective cross-examination of experts guaranteed in Rule 26(b)(4). The court of appeals underscored its error by incorrectly saying that the government did not conceal the Whitley article. (A-7). But concealment is not the test. By unfairly placing the burden of such a showing on the victims of the tainted evidence — the Stichs — rather

than on the errant party, the court drastically altered the procedural relations of the parties in federal trials in favor of the wrongdoer. Such a result can not be justified as an "exercise of discretion," and warrants review by this Court.

> "Rule 26(e) does not contain any specific sanction for failure to supplement discovery. Nevertheless, '[f]ew would question a court's inherent power to discipline breaches of [the rule], even in the absence of a court order.' *Discovery sanctions are commonly left to the discretion of the trial court, but as a reviewing court we are not prevented from stepping in where, as in this case, the exercise of that discretion effectively rewards the errant party and unwarrantedly prejudices his opposition.*" (emphasis added).

*Labadie Coal Company v. Black*, 672 F.2d 92, 95 (D.C. Cir. 1982).

Review by this Court is essential to ensure public confidence in the fairness and integrity of public health programs. Accordingly, the petition for a writ of certiorari to the United States Court of Appeals for the Third Circuit should be granted.

Respectfully submitted,

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